

chickens should consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; do not administer within 24 hours of slaughter .

(2) *Turkeys*—(i) *Amount*. 2 grams per gallon.

(ii) *Indications for use*. Maintaining weight gains and feed efficiency in the presence of infectious sinusitis caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations*. Do not use in layers producing eggs for human consumption; administer from 2 to 5 days as sole source of drinking water; treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; when sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment; do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount*. 0.25 gram per gallon.

(ii) *Indications for use*. For the control and treatment of swine dysentery (bloody scours) caused by pathogens sensitive to tylosin.

(iii) *Limitations*. As only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated; mix fresh solution daily; medication must be withheld from animals 48 hours prior to slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994; 62 FR 39443, July 23, 1997; 68 FR 24879, May 9, 2003]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

Sec.

522.23 Acepromazine maleate injection.
 522.44 Sterile sodium acetazolamide.
 522.46 Alfaprostol.
 522.56 Amikacin sulfate injection.
 522.62 Aminopentamide hydrogen sulfate injection.
 522.82 Aminopropazine fumarate sterile solution injection.
 522.84 Beta-aminopropionitrile fumarate.
 522.88 Sterile amoxicillin trihydrate for suspension.

522.90 Ampicillin implantation and injectable dosage forms.
 522.90a Ampicillin trihydrate sterile suspension.
 522.90b Ampicillin trihydrate for sterile suspension.
 522.90c Ampicillin sodium for aqueous injection.
 522.144 Arsenamide sodium aqueous injection.
 522.147 Atipamezole hydrochloride.
 522.150 Azaperone injection.
 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.
 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.
 522.204 Boldenone undecylenate injection.
 522.234 Butamisol hydrochloride.
 522.246 Butorphanol tartrate injection.
 522.311 Carfentanil citrate injection.
 522.312 Carprofen.
 522.313 Ceftiofur sodium powder for injection.
 522.314 Ceftiofur hydrochloride.
 522.315 Ceftiofur crystalline free acid.
 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.
 522.390 Chloramphenicol injection.
 522.460 Cloprostenol sodium.
 522.468 Colistimethate sodium powder for injection.
 522.480 Repository corticotropin injection.
 522.518 Cupric glycinate injection.
 522.522 Danofloxacin.
 522.533 Deslorelin acetate.
 522.535 Desoxycorticosterone pivalate.
 522.536 Detomidine hydrochloride injection.
 522.540 Dexamethasone injection.
 522.542 Dexamethasone-21-isonicotinate suspension.
 522.563 Diatrizoate meglumine and diatrizoate sodium injection.
 522.575 Diazepam injection.
 522.650 Dihydrostreptomycin sulfate injection.
 522.690 Dinoprost solution.
 522.723 Diprenorphine hydrochloride injection.
 522.770 Doramectin.
 522.775 Doxapram hydrochloride injection.
 522.778 Doxycycline hyclate.
 522.784 Doxylamine succinate injection.
 522.800 Droperidol and fentanyl citrate injection.
 522.812 Enrofloxacin solution.
 522.820 Erythromycin injection.
 522.840 Estradiol.
 522.841 Estradiol benzoate.
 522.842 Estradiol benzoate and testosterone propionate in combination.
 522.850 Estradiol valerate and norgestomet in combination.
 522.863 Ethylisobutrazine hydrochloride injection.

- 522.883 Etorphine hydrochloride injection.
 522.900 Euthanasia solution.
 522.914 Fenprostalene solution.
 522.940 Colloidal ferric oxide injection.
 522.955 Florfenicol.
 522.960 Flumethasone implantation or injectable dosage forms.
 522.960a Flumethasone suspension.
 522.960b Flumethasone acetate injection.
 522.960c Flumethasone solution.
 522.970 Flunixin meglumine solution.
 522.995 Fluprostenol sodium injection.
 522.1002 Follicle stimulating hormone.
 522.1004 Fomepizole.
 522.1010 Furosemide.
 522.1020 Gelatin solution.
 522.1044 Gentamicin sulfate injection.
 522.1055 Gleptoferron injection.
 522.1066 Glycopyrrolate injection.
 522.1077 Gonadorelin injectable.
 522.1078 Gonadorelin diacetate tetrahydrate.
 522.1079 Serum gonadotropin and chorionic gonadotropin.
 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.
 522.1085 Guaifenesin sterile powder.
 522.1086 Guaifenesin injection.
 522.1125 Hemoglobin glutamer-200 (bovine).
 522.1145 Hyaluronate sodium injection.
 522.1150 Hydrochlorothiazide injection.
 522.1155 Imidocarb dipropionate sterile powder.
 522.1156 Imidocarb dipropionate solution.
 522.1182 Iron dextran complex injection.
 522.1183 Iron hydrogenated dextran injection.
 522.1192 Ivermectin injection.
 522.1193 Ivermectin and clorsulon injection.
 522.1204 Kanamycin sulfate injection.
 522.1222 Ketamine hydrochloride injectable dosage forms.
 522.1222a Ketamine.
 522.1222b Ketamine hydrochloride with promazine hydrochloride and aminopentamide hydrogen sulfate injection.
 522.1225 Ketoprofen solution.
 522.1228 [Reserved]
 522.1244 Levamisole phosphate injection.
 522.1260 Lincomycin.
 522.1289 Lufenuron suspension.
 522.1290 Luprostitol sterile solution.
 522.1335 Medetomidine hydrochloride injection.
 522.1350 Melatonin implant.
 522.1362 Melarsomine dihydrochloride for injection.
 522.1367 Meloxicam.
 522.1372 Mepivacaine hydrochloride injection.
 522.1380 Methocarbamol injection.
 522.1410 Sterile methylprednisolone acetate suspension.
 522.1451 Moxidectin.
 522.1452 Nalorphine hydrochloride injection.
 522.1462 Naloxone hydrochloride injection.
 522.1465 Naltrexone hydrochloride injection.
 522.1468 Naproxen for injection.
 522.1484 Neomycin sulfate sterile solution.
 522.1503 Neostigmine methylsulfate injection.
 522.1610 Oleate sodium solution.
 522.1620 Orgotein for injection.
 522.1642 Oxymorphone hydrochloride injection.
 522.1660 Oxytetracycline injection, 200 milligram/milliliter.
 522.1660a Oxytetracycline injection, 300 milligram/milliliter.
 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.
 522.1662a Oxytetracycline hydrochloride injection.
 522.1662b Oxytetracycline hydrochloride with lidocaine injection.
 522.1680 Oxytocin injection.
 522.1696 Penicillin G procaine implantation and injectable dosage forms.
 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.
 522.1696b Penicillin G procaine aqueous suspension.
 522.1696c Penicillin G procaine in oil.
 522.1698 Pentazocine lactate injection.
 522.1704 Sodium pentobarbital injection.
 522.1720 Phenylbutazone injection.
 522.1820 Pituitary luteinizing hormone for injection.
 522.1850 Polysulfated glycosaminoglycan.
 522.1862 Sterile pralidoxime chloride.
 522.1870 Praziquantel injectable solution.
 522.1881 Sterile prednisolone acetate aqueous suspension.
 522.1883 Prednisolone sodium phosphate.
 522.1884 Prednisolone sodium succinate injection.
 522.1885 Prednisolone tertiary butylacetate suspension.
 522.1890 Sterile prednisone suspension.
 522.1920 Prochlorperazine, isopropamide for injection.
 522.1940 Progesterone and estradiol benzoate in combination.
 522.1962 Promazine hydrochloride.
 522.2002 Propiopromazine hydrochloride injection.
 522.2005 Propofol injection.
 522.2012 Prostalene solution.
 522.2063 Pyrilamine maleate injection.
 522.2100 Selenium, vitamin E injection.
 522.2112 Sometribove zinc suspension.
 522.2120 Spectinomycin dihydrochloride injection.
 522.2121 Spectinomycin sulfate solution.
 522.2150 Stanozolol sterile suspension.
 522.2200 Sulfachlorpyridazine.
 522.2220 Sulfadimethoxine injection.
 522.2240 Sulfaethoxypyridazine.
 522.2260 Sulfamethazine injectable solution.
 522.2340 Sulfomyxin.
 522.2404 Thialbarbitone sodium for injection.
 522.2424 Sodium thiamylal for injection.

§ 522.23

- 522.2444 Sodium thiopental implantation or injectable dosage forms.
522.2444a Sodium thiopental for injection.
522.2444b Sodium thiopental, sodium pentobarbital for injection.
522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.
522.2471 Tilmicosin.
522.2474 Tolazoline hydrochloride injection.
522.2476 Trenbolone acetate.
522.2477 Trenbolone acetate and estradiol.
522.2478 Trenbolone acetate and estradiol benzoate.
522.2483 Sterile triamcinolone acetonide suspension.
522.2582 Triflupromazine hydrochloride injection.
522.2610 Trimethoprim and sulfadiazine sterile suspension.
522.2615 Tripelennamine hydrochloride injection.
522.2640 Tylosin injectable dosage forms.
522.2640a Tylosin injection.
522.2662 Xylazine.
522.2670 Yohimbine injectable.
522.2680 Zeranol.
522.2690 Zinc gluconate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

§ 522.23 Acepromazine maleate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of acepromazine maleate.

(b) *Conditions of use.* See No. 000856 and 059130 in § 510.600(c) of this chapter for use in dogs, cats, and horses as follows:

(1) *Indications for use.* It is used in dogs, cats, and horses as a tranquilizer.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.

(c) *Conditions of use.* See No. 000010 in § 510.600(c) of this chapter for use in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight.

(3) *Limitations.* The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law

21 CFR Ch. I (4–1–04 Edition)

restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 43831, Sept. 1, 1981, as amended at 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 68 FR 33856, June 6, 2003]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.¹

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 522.46 Alfaprostol.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of alfaprostol.

(b) *Sponsor.* No. 055882 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses as follows:

(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

Food and Drug Administration, HHS

§ 522.82

bronchial spasms. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 43300, Sept. 23, 1983, as amended at 53 FR 40057, Oct. 13, 1988]

§ 522.56 Amikacin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 5 milligrams per pound of body weight twice daily.

(2) *Indications for use.* The drug is used in dogs for treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(3) *Limitations.* The drug is administered intramuscularly or subcutaneously. Treat dogs with skin and soft tissue infections for a minimum of 7 days and those with genitourinary infections for 7 to 21 days or until culture is negative and asymptomatic. If no response is observed after 3 days of treatment, therapy should be discontinued and the case re-evaluated. Maximum duration of therapy should not exceed 30 days. Systemic aminoglycoside therapy is contraindicated in dogs with seriously impaired renal function. Not for use in breeding dogs as reproductive studies have not been conducted. Use with extreme caution in dogs in which hearing acuity is required for functioning. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 11816, Apr. 13, 1987; 52 FR 15412, Apr. 28, 1987, as amended at 53 FR 27851, July 25, 1988; 62 FR 23357, Apr. 30, 1997]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use dosage may be continued by oral administration of tablets.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 522.82 Aminopropazine fumarate sterile solution injection.

(a) *Specifications.* Each milliliter of aminopropazine fumarate sterile aqueous solution, veterinary, contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis in cats and dogs and in colic spasms in horses.¹

(2) It is administered intramuscularly or intravenously to

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 522.84

21 CFR Ch. I (4-1-04 Edition)

dogs and cats at a level of 1 to 2 milligrams per pound of body weight. It is administered intramuscularly or intravenously to horses at a level of 0.25 milligrams per pound of body weight. Dosage can be repeated every 12 hours, as indicated.¹

(3) Not for use in animals intended for food purposes.¹

(4) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.84 **Beta-aminopropionitrile fumarate.**

(a) *Specifications.* Each vial contains 7.0 milligrams of beta-aminopropionitrile fumarate sterile lyophilized powder which is reconstituted for injection with 10 milliliters of sterile physiologic saline, USP.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 7 milligrams (10 milliliters) intralesionally every other day for 5 treatments beginning about 30 days after initial injury.

(ii) *Indications for use.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in the adult horse where there is sonographic evidence of fiber tearing.

(iii) *Limitations.* Single dose container for intralesional injection. Do not use in horses with dermal irritation or open skin lesions in the injection area. Do not administer intraarticularly, into the tendon sheath, or in the presence of concurrent limb fractures. Do not use in breeding animals since the effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44382, Aug. 19, 1998]

§ 522.88 **Sterile amoxicillin trihydrate for suspension.**

(a)(1) *Specifications.* Each vial contains 3 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to

a concentration of 100 or 250 milligrams per milliliter for use as in paragraph (d) of this section.

(2) Each vial contains 25 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 250 milligrams per milliliter for use as in paragraph (e).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.38 of this chapter.

(d) *Conditions of use in dogs and cats*—

(1) *Amount.* 5 milligrams per pound of body weight daily.

(2) *Indications for use*—(i) *Dogs.* Treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(ii) *Cats.* Treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(3) *Limitations.* For use in dogs and cats only. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, re-evaluate the diagnosis and change therapy.

As with all antibiotics, appropriate in vitro culturing susceptibility testing of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Condition of use. Cattle*—(1) *Amount.* 3 to 5 milligrams per pound of body weight once a day according to the animal being treated, the severity of infection, and the animal's response.

(2) *Indications for use.*— Treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida*, *P. hemolytica*, *Hemophilus* spp., *Staphylococcus* spp., and *Streptococcus* spp. and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum*.

(3) *Limitations.* Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Do not continue treatment beyond 5 days. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Maximum volume per injection should not exceed 30 milliliters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992; 60 FR 55659, Nov. 2, 1995]

§ 522.90 Ampicillin implantation and injectible dosage forms.

§ 522.90a Ampicillin trihydrate sterile suspension.

(a) *Specifications.* Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams of ampicillin.

(1) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(2) *Related tolerances.* See § 556.40 of this chapter.

(3) *Conditions of use*—(i) *Calves.*

(A) *Amount.* For enteritis: 3 milligrams per pound of body weight,

intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 milligrams per pound of body weight, intramuscularly, twice daily, for up to 3 days.

(B) *Indications for use.* Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(C) *Limitations.* Not for use in other animals raised for food production. Treated animals must not be slaughtered for food use during treatment or for 9 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Dogs.* (A) *Amount.* 3 to 6 milligrams per pound of body weight intramuscularly, once or twice daily.

(B) *Indications for use.* Treatment of respiratory tract infections due to *E. coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; tonsillitis due to *E. coli*, *Pseudomonas* spp., *Streptococcus* spp., and *Staphylococcus* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(C) *Limitations.* Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Cats.* (A) *Amount.* 5 to 10 milligrams per pound of body weight intramuscularly or subcutaneously, once or twice daily.

(B) *Indications for use.* Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

(C) *Limitations.* Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Swine.* (A) *Amount.* 3 milligrams per pound of body weight,

§ 522.90b

21 CFR Ch. I (4-1-04 Edition)

intramuscularly, once or twice daily, for up to 3 days.

(B) *Indications for use.* Treatment of bacterial enteritis (colibacillosis) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(C) *Limitations.* Treated animals must not be slaughtered for food use during treatment or for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) *Specifications.* Each milliliter contains ampicillin trihydrate equivalent to 150 milligrams of ampicillin.

(1) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(2) *Related tolerances.* See § 556.40 of this chapter.

(3) *Conditions of use. Dogs—(i) Amount.* 3 to 5 milligrams of ampicillin per pound of body weight, once a day for up to 4 days.

(ii) *Indications for use.* Treatment of bacterial infections of the upper respiratory tract (tonsillitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli*, *Proteus* spp., and *Pasteurella* spp., and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*, when caused by susceptible organisms.

(iii) *Limitations.* Administer intramuscularly. If continued treatment is indicated, oral dosage is recommended. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment are recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 522.90b Ampicillin trihydrate for sterile suspension.

(a) *Specifications.* When reconstituted, each milliliter contains ampicillin trihydrate equivalent to 50, 100, or 250 milligrams of ampicillin.

(b) *Sponsor.* (1) See 000856 in § 510.600(c) of this chapter for use of 50, 100, and 250 milligrams per milliliter ampicillin suspension.

(2) See 010515 in § 510.600(c) of this chapter for use of 100 and 250 milli-

grams per milliliter ampicillin suspension.

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use. (1) Dogs—(i) Amount.* 3 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount.* 3 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle—(i) Amount.* 2 to 5 milligrams per pound of body weight once daily by intramuscular injection.

(ii) *Indications for use.* Treatment of respiratory tract infections caused by organisms susceptible to ampicillin, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida*, and *Escherichia coli*.

(iii) *Limitations.* Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment and for 144 hours (6 days) after the last treatment. Federal

Food and Drug Administration, HHS

§ 522.150

law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993; 63 FR 41420, Aug. 4, 1998]

§ 522.90c Ampicillin sodium for aqueous injection.

(a) *Specifications.* When reconstituted, each milliliter contains ampicillin sodium equivalent to 300 milligrams of ampicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use. Horses—*(1) *Amount:* 3 milligrams per pound of body weight twice daily.

(2) *Indications for use.* Treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(3) *Limitations.* Administer either intravenously or intramuscularly. Treatment should be continued 48 hours after all symptoms have subsided. If no response is seen in 4 to 5 days, reevaluate diagnosis. Not for use in horses or other animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 522.144 Arsenamide sodium aqueous injection.

(a) *Chemical name.* [[(*p*-Carbamoylphenyl) arsylene]dithio diacetic acid, sodium salt.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains 10.0 milligrams of arsenamide sodium.

(c) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis*.

(2) It is administered intravenously at 0.1 milliliter per pound of body weight (1.0 milliliter for every 10 pounds) twice a day for 2 days. For dogs in poor condition, particularly

those with evidence of reduced liver function, a more conservative dosage schedule of 0.1 milliliter per pound of body weight daily for 15 days is recommended.

(3) Restricted to use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 27785, June 27, 1978; 45 FR 56798, Aug. 26, 1980; 55 FR 26683, June 29, 1990]

§ 522.147 Atipamezole hydrochloride.

(a) *Specifications.* Each milliliter of sterile injectable solution contains 5.0 milligrams of atipamezole hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*(1) *Amount.* Inject intramuscularly the same volume as that of medetomidine used.

(2) *Indications for use.* To reverse clinical effects of the sedative and analgesic agent medetomidine hydrochloride.

(3) *Limitations.* For intramuscular use only. Not recommended for use in pregnant or lactating animals, or animals intended for breeding. Atipamezole has not been evaluated in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 48830, Sept. 17, 1996, as amended at 64 FR 71640, Dec. 22, 1999]

§ 522.150 Azaperone injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 40 milligrams of azaperone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Indications for use.* Control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 milligrams per kilogram (1 milligram per pound).

(3) *Limitations.* Inject by deep intramuscular injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 48229, Oct. 18, 1983, as amended at 62 FR 61625, Nov. 19, 1997]

§ 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.

(a) *Chemical names.* Betamethasone acetate: 9- α -Fluoro-16- β -methylprednisolone - 21 - acetate (C₂₄H₃₁FO₆). Betamethasone disodium phosphate: 9- α -Fluoro-16- β -methylprednisolone-21-disodium phosphate (C₂₂H₂₈FN₂O₈P).

(b) *Specifications.* The drug is a sterile aqueous suspension and each cubic centimeter contains: 12 milligrams of betamethasone acetate (equivalent to 10.8 milligrams of betamethasone), 3.9 milligrams of betamethasone disodium phosphate (equivalent to 3 milligrams of betamethasone), 2 milligrams of dibasic sodium phosphate, 5 milligrams of sodium chloride, 0.1 milligram of disodium EDTA, 0.5 milligram of polysorbate 80, 9 milligrams of benzyl alcohol, 5 milligrams of sodium carboxymethylcellulose, 1.8 milligrams of methylparaben, 0.2 milligram of propylparaben, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection q.s.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* It is used or intended for use by intra-articular injection of horses for the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpal and fetlock joints. Administer from 2.5 to 5 cubic centimeters per dose. Dose may be repeated when necessary depending upon the duration of relief obtained. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.

(a) *Specifications.* Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension is a sterile aqueous suspension. Each milliliter of the suspension contains the equivalent of 5 milligrams of betamethasone as betamethasone dipropionate and 2 milligrams of betamethasone as betamethasone sodium phosphate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs.* (i) It is used as an aid in the control of pruritus associated with dermatoses.

(ii) It is administered by intramuscular injection at a dosage of 0.25 to 0.5 milliliter per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of 4 injections.

(2) *Horses.* (i) It is used as an aid in the control of inflammation associated with various arthropathies.

(ii) It is administered aseptically by intraarticular injection at a dosage of 2.5 to 5 milliliters per joint, depending on the severity of the condition and the joint size. Dosage may be repeated upon recurrence of clinical signs. Injection into the joint cavity should be preceded by withdrawal of synovial fluid.

(iii) Not for use in horses intended for food.

(3) *Clinical and experimental data.* It has been demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) *Restrictions.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 27316, July 2, 1976; 52 FR 7832, Mar. 13, 1987]

§ 522.204 Boldenone undecylenate injection.

(a) *Specifications.* Each milliliter contains 25 or 50 milligrams of boldenone undecylenate in a sesame oil base.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use as an aid in treating debilitated horses following disease or overwork and overexertion when an improvement in weight, hair coat, or general physical condition is desired. The drug is given only as adjunctive therapy to

other specific and supportive therapy for diseases, surgical cases, and traumatic injuries. Optimal results can be expected only when good management and feeding practices are followed.

(2) It is administered intramuscularly at a dosage level of 0.5 milligram per pound of body weight. Treatment may be repeated at 3-week intervals.

(3) For use in horses only. Do not administer to horses intended for use as food. The effectiveness of the drug in stallions and pregnant mares has not been established, nor has the drug been shown not to be teratogenic in pregnant mares; therefore, this drug should not be used in stallions and pregnant mares.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 522.234 Butamisol hydrochloride.

(a) *Specifications.* The drug contains 11 milligrams of butamisol per milliliter in a solution consisting of 70 percent propylene glycol, 4 percent benzyl alcohol and distilled water.

(b) *Sponsor.* See Nos. 000859 and 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered by subcutaneous injection to dogs for the treatment of infections with whipworms (*Trichuris vulpis*), and the hookworm (*Ancylostoma caninum*).

(2) The drug is administered subcutaneously at the rate of 0.1 milliliter per pound of body weight. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 15625, Apr. 14, 1978. Redesignated at 43 FR 60883, Dec. 29, 1978, and amended at 45 FR 29789, May 6, 1980; 51 FR 19329, May 29, 1986; 67 FR 63055, Oct. 10, 2002]

§ 522.246 Butorphanol tartrate injection.

(a) *Specifications.* Each milliliter of aqueous solution contains either 0.5, 2

or 10 milligrams of butorphanol (as butorphanol tartrate).

(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See Nos. 057926 and 059130 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.025 milligram of butorphanol base activity per pound of body weight (equivalent to 0.5 milliliter per 10 pounds), using 0.5 milligram per milliliter solution.

(ii) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(iii) *Limitations.* For subcutaneous injection in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to maximum of 0.05 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* 0.05 milligram of butorphanol base activity per pound of body weight (0.1 milligram/kilogram) using 10 milligrams per milliliter solution.

(ii) *Indications for use.* For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) *Limitations.* For intravenous use in horses only. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cats*—(i) *Amount.* 0.2 milligram of butorphanol base activity per pound of body weight (0.4 milligram/kilogram), using 2 milligrams per milliliter solution.

(ii) *Indications for use.* For the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures.

§ 522.311

(iii) *Limitations.* For subcutaneous injection in cats only. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days. Safety for use in pregnant female cats, breeding male cats or kittens less than 4 months of age has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 29276, May 2, 1980, as amended at 50 FR 24508, June 11, 1985; 53 FR 27851, July 25, 1988; 59 FR 41665, Aug. 15, 1994; 63 FR 66432, Dec. 2, 1998; 68 FR 22594, Apr. 29, 2003]

§ 522.311 Carfentanil citrate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 3 milligrams of carfentanil citrate.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 5 to 20 micrograms per kilogram (.005 to .020 milligram per kilogram) of body weight.

(2) *Indications for use.* For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) *Limitations.* Inject into large muscle of neck, shoulder, back, or hindquarter. Avoid intrathoracic, intra-abdominal, or subcutaneous injection. To reverse effect, use 7 milligrams of diprenorphine for each milligram of carfentanil citrate, given intravenously or one-half intravenously and one-half intramuscularly or subcutaneously. Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Do not use in animals that display clinical signs of severe cardiovascular or respiratory disease. Available data are inadequate to recommend use in pregnant animals. Avoid use during breeding season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

[53 FR 40057, Oct. 13, 1988]

§ 522.312 Carprofen.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) carprofen.

21 CFR Ch. I (4–1–04 Edition)

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs—(1) Amount.* 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Conditions of use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26205, May 15, 2003, as amended at 68 FR 34796, June 11, 2003; 68 FR 49351, Aug. 18, 2003]

§ 522.313 Ceftiofur sodium powder for injection.

(a) *Specifications.* Ceftiofur sodium sterile powder for injection is reconstituted to form an aqueous solution containing the equivalent of 50 milligrams ceftiofur per milliliter.

(b) *Sponsor.* See 000009 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use—(1) Cattle—(i) Amount.* 0.5 to 1.0 milligram of ceftiofur per pound of body weight intramuscularly or subcutaneously.

(ii) *Indications for use.* Treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Pasteurella hemolytica*, *P. multocida*, and *Haemophilus somnus* in beef and dairy cattle. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations.* Treatment should be repeated once every 24 hours for 3 days. Treat for an additional 2 days if animals do not show a satisfactory response. Do not use in animals previously found to be hypersensitive to the drug. Use of doses in excess of those indicated may result in illegal residues in tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. 3 to 5 milligrams per kilogram (1.36 to 2.27 milligrams per pound) of body weight.

(ii) *Indications for use*. For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus (Haemophilus) pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis* Type 2.

(iii) *Limitations*. For intramuscular use only. Treatment should be repeated at 24 hour intervals for a total of 3 consecutive days. Do not use in animals previously found to be hypersensitive to the drug. Use of dosages in excess of those indicated or route of administration other than that recommended may result in illegal residues in tissues. Safety of ceftiofur has not been determined in breeding swine. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Day-old chickens*—(i) *Amount*. 0.08 to 0.20 milligram per chick.

(ii) *Indications for use*. For control of early mortality associated with *Escherichia coli* organisms susceptible to ceftiofur.

(iii) *Limitations*. For subcutaneous use in the neck of day-old chicks only. As a single dose only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Day-old turkey poults*—(i) *Amount*. 0.17 to 0.5 milligram per poult.

(ii) *Indications for use*. For control of early mortality associated with *E. coli* organisms susceptible to ceftiofur.

(iii) *Limitations*. For subcutaneous use in the neck of day-old poults only. As a single dose only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Horses*—(i) *Amount*. 2.2 to 4.4 milligrams per kilogram (1.0 to 2.0 milligrams per pound) of body weight.

(ii) *Indications for use*. For treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus*.

(iii) *Limitations*. For intramuscular use only. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 milliliters should be administered per injection site. Not for use in horses intended for food. Do not use in

animals previously found to be hypersensitive to the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(6) *Dogs*—(i) *Amount*. 1.0 milligrams per pound (2.2 milligrams per kilogram) of body weight.

(ii) *Indications for use*. Treatment of canine urinary tract infections associated with *Escherichia coli* and *Proteus mirabilis*.

(iii) *Limitations*. For subcutaneous use only. Treatment should be repeated at 24-hour intervals, continued for 48 hours after clinical signs have disappeared, for 5 to 14 days. Do not use in animals found to be hypersensitive to the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(7) *Sheep*—(i) *Amount*. 0.5 to 1.0 milligram per pound (1.1 to 2.2 milligrams per kilogram) of body weight.

(ii) *Indications for use*. For treatment of sheep respiratory disease (pneumonia) associated with *Pasteurella haemolytica* and/or *P. multocida*.

(iii) *Limitations*. For intramuscular use only. Treatment should be repeated at 24 hour intervals for a total of 3 consecutive days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(8) *Goats*—(i) *Amount*. 0.5 to 1.0 milligram per pound of body weight by intramuscular injection at 24-hour intervals for a total of 3 consecutive days. Additional treatments may be given on days 4 and 5 for animals that do not show satisfactory response.

(ii) *Indications for use*. For treatment of caprine respiratory disease (goat pneumonia) associated with *Pasteurella haemolytica* and *P. multocida*.

§ 522.314

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[53 5369, Feb. 24, 1988, as amended at 55 FR 13768, Apr. 12, 1990; 56 FR 12119, Mar. 22, 1991; 57 FR 41862, Sept. 14, 1992; 59 FR 41666, Aug. 15, 1994; 59 FR 54518, Nov. 1, 1994; 60 FR 51719, Oct. 3, 1995; 61 FR 35130, July 5, 1996; 61 FR 66583, Dec. 18, 1996; 66 FR 21283, Apr. 30, 2001; 66 FR 32540, June 15, 2001]

§ 522.314 Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of suspension contains ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use.* (1) *Swine*—(i) *Amount.* 3 to 5 mg per kilogram (kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis* Type 2.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Dosage.* 1.1 to 2.2 mg/kg of body weight by intramuscular or subcutaneous injection, at 24-hour intervals for 3 to 5 consecutive days. For bovine respiratory disease, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis, administer 2.2 mg/kg of body weight daily for 5 consecutive days.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia* spp. (*Pasteurella haemolytica*), *P. multocida*, and *Haemophilus somnus*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melanogenicus*; and acute metritis (0 to 14 days post partum) associated with bacteria susceptible to ceftiofur.

21 CFR Ch. I (4–1–04 Edition)

(iii) *Limitations.* Do not slaughter treated cattle for 48 hours (2 days) after last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 29479, June 11, 1996, as amended at 63 FR 53578, Oct. 6, 1998; 67 FR 45901, July 11, 2002]

§ 522.315 Ceftiofur crystalline free acid.

(a) *Specifications.* Each milliliter of suspension contains 200 milligrams (mg) ceftiofur equivalents (CE).

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 6.6 mg CE per kilogram of body weight by a single, subcutaneous injection in the middle third of the posterior aspect of the ear.

(2) *Indications for use.* For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somnus*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

[68 FR 60296, Oct. 22, 2003]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

(a) [Reserved]

(b)(1) *Specifications.* Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution contains 42.5 milligrams of chloral hydrate, 8.86 milligrams of pentobarbital, and 21.2 milligrams of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 33.8 percent propylene glycol, and 14.25 percent ethyl alcohol.

(2) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for general anesthesia and as a sedative-relaxant in cattle and horses.

(ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 milliliters per 100 pounds of body weight for general anesthesia until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 45 FR 16482, Mar. 14, 1980]

§ 522.390 Chloramphenicol injection.

(a) *Specifications.* Each milliliter contains 100 milligrams of chloramphenicol.

(b) *Sponsor.* See Nos. 000069 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Amount.* 5 to 15 milligrams per pound of body weight, intramuscularly or intravenously, every 6 hours. In severe infections, use 4 to 6 hour treatment intervals the first day. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000]

§ 522.460 Cloprostenol sodium.

(a)(1) *Specifications.* Each milliliter of the aqueous solution contains 263 micrograms of cloprostenol sodium (equivalent to 250 micrograms of cloprostenol) in a sodium citrate, anhydrous citric acid and sodium chloride buffer containing 0.1 percent w/v chlorocresol B.P. as a bactericide.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* For intramuscular use in beef and dairy cattle to induce luteolysis.

(i) *Amount.* 2 milliliters (equivalent to 500 micrograms of cloprostenol).

(ii) *Indications.* (a) For scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(1) *Single cloprostenol injection.* Treat only animals with a mature corpus luteum. Estrus should occur in 2 to 5 days, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at 72 hours post injection or twice at 72 and 96 hours post injection.

(2) *Double cloprostenol injection.* Give cattle a second injection 11 days after the first injection. Estrus should occur 2 to 5 days after the second injection, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at about 72 hours post injection or twice at 72 and 96 hours following the second injection.

(b) *Single cloprostenol injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception, or for treating unobserved (non-detected) estrus, mummified fetus, and luteal cysts.*

(c) *Single cloprostenol injection for the treatment of pyometra.*

(iii) Do not administer to pregnant animals where the calf is not to be aborted.

(iv) Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Cloprostenol is readily absorbed through the skin and may cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 131.5 micrograms of cloprostenol sodium

§ 522.468

(equivalent to 125 micrograms of cloprostenol).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Special considerations.* Labeling shall bear the statements prescribed in paragraphs (a)(3) (iii) and (iv) of this section.

(4) *Conditions of use—(i) Amount.* 3 milliliters (equivalent to 375 micrograms of cloprostenol) intramuscularly per animal as a single dose.

(ii) *Indications for use.* To induce abortion in pregnant feedlot heifers from 1 week after mating until 4½ months of gestation.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 4678, Feb. 2, 1982, as amended at 48 FR 15619, Apr. 12, 1983; 49 FR 5100, Feb. 10, 1984; 49 FR 29957, July 25, 1984; 65 FR 6892, Feb. 11, 2000]

§ 522.468 Colistimethate sodium powder for injection.

(a) *Specifications.* Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) *Sponsor.* See 046573 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) 1- to 3-day-old chickens.

(i) *Dosage.* 0.2 milligram colistin activity per chicken.

(ii) *Indications for use.* Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations.* For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13123, Mar. 18, 1998]

21 CFR Ch. I (4-1-04 Edition)

§ 522.480 Repository corticotropin injection.

(a)(1) *Specifications.* The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.C. (I.U.) units per cubic centimeter.

(2) *Sponsor.* See No. 037990 in § 510.600(c) of this chapter.

(3) *Special considerations.* The drug should be refrigerated. With prolonged use supplement daily diet with potassium chloride at one gram for small animals and from 5 to 10 grams for large animals.

(4) *Conditions of use.* (i) It is used as an intramuscular or subcutaneous injection in cattle and small animals for stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH). It is also a therapeutic agent for primary bovine ketosis.

(ii) It is administered to cattle initially at 200 to 600 units followed by a dose daily or every other day of 200 to 300 units and to small animals at one unit per pound of body weight to be repeated as indicated.

(iii) For use only by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.P. units per milliliter.

(2) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) For intramuscular injection in dogs as a diagnostic aid to test for adrenal dysfunction. For intramuscular or subcutaneous injection in dogs and cats for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

(ii) For diagnostic use: Administer at one unit per pound of body weight intramuscularly. For therapeutic use: Administer at one unit per pound of body weight intramuscularly or subcutaneously, initially, to be repeated as indicated.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The therapeutic indication for use has been reviewed by NAS/NRC and found to be effective. Applications for

Food and Drug Administration, HHS

§ 522.535

this use need not include effectiveness data as specified in §514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13858, Mar. 27, 1985, as amended at 50 FR 40966, Oct. 8, 1985; 53 FR 45760, Nov. 14, 1988; 68 FR 59881, Oct. 20, 2003]

§ 522.518 Cupric glycinate injection.

(a) *Specifications.* Each milliliter (mL) of sterile aqueous suspension contains 200 milligrams of cupric glycinate (equivalent to 60 milligrams of copper).

(b) *Sponsor.* See No. 049185 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 200 milligrams (1 mL) for calves 300 pounds and under; 400 milligrams (2 mL) for calves over 300 pounds and adult cattle.

(2) *Indications for use.* For beef calves and beef cattle for the prevention of copper deficiency, or when labeled for veterinary prescription use, for the prevention and/or treatment of copper deficiency alone or in association with molybdenum toxicity.

(3) *Limitations.* For subcutaneous use only; repeat dose in 3 months in young calves, in 6 months in cattle; discontinue use 30 days before treated animals are slaughtered for food use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 20159, Apr. 3, 1981, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 28630, May 27, 1997]

§ 522.522 Danofloxacin.

(a) *Specifications.* Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

(b) *Sponsor.* See No. 000069 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 6 mg per kilogram of body weight by subcutaneous injection. Treatment should be repeated approximately 48 hours following the first injection.

(2) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*.

(3) *Limitations.* Animals intended for human consumption should not be slaughtered within 4 days from the last

treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[67 FR 78972, Dec. 27, 2002]

§ 522.533 Deslorelin acetate.

(a) *Specifications.* Each implant contains 2.1 milligrams deslorelin acetate.

(b) *Sponsor.* See 064288 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount.* One implant per mare.

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

(iii) *Limitations.* Administer subcutaneously in the neck. Not for use in horses or ponies intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44383, Aug. 19, 1998]

§ 522.535 Desoxycorticosterone pivalate.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) *Sponsor.* See No. 058198 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use.* For use as replacement therapy for the

mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations.* For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998]

§ 522.536 Detomidine hydrochloride injection.

(a) *Specification.* Each milliliter of sterile aqueous solution contains 10 milligrams of detomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required.

(2) *Indication for use.* As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(3) *Limitations.* For sedation administer intravenously (IV) or intramuscularly (IM); for analgesia by IV; for both sedation and analgesia by IV. Do not use in horses with pre-existing atrioventricular or sinoauricular block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in breeding animals. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50365, Dec. 6, 1989; 54 FR 51551, Dec. 15, 1989]

§ 522.540 Dexamethasone injection.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 059130, and 061623 for use as in paragraph (a)(3) of this section.

(ii) No. 000857 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use—(i) Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains either 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams dexamethasone).

(2) *Sponsor.* See number in § 510.600(c) of this chapter as follows:

(i) No. 061623 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(ii) No. 000402 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(3) *Conditions of use.* (i) The drug is used in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor surgical risks, and as supportive therapy in nonspecific dermatosis.¹

(ii) The drug is administered intravenously at 0.25 to 1 milligram initially. The dose may be repeated for 3 to 5 days or until a response is noted. If continued treatment is required, oral therapy may be substituted. When

¹These conditions are NAS/NRC-reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

therapy is withdrawn after prolonged use, the daily dose should be reduced gradually over several days.¹

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams of dexamethasone).

(2) *Sponsor.* See Nos. 000402 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used as a rapid adrenal glucocorticoid and/or anti-inflammatory agent in horses.¹

(ii) The drug is administered intravenously at a dosage of 2.5 to 5.0 milligrams. If permanent corticosteroid effect is required, oral therapy may be substituted. When therapy is withdrawn after prolonged use, the daily dose should be reduced gradually over several days.¹

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(iv) Not for use in horses intended for food.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams of dexamethasone).

(2) *Sponsors.* See the following numbers in § 510.600(c) of this chapter:

(i) Nos. 000069 and 059130 for intravenous or intramuscular use of 2.0 milligrams dexamethasone injection.

(ii) No. 000069 for intravenous use of 2.0 milligrams dexamethasone injection.

(3) *Conditions of use.* (i) The drug is used as an anti-inflammatory agent in dogs, cats, and horses.

(ii) It is administered intravenously or intramuscularly as follows: dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—2.5 to 5 milligrams.

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(iv) Not for use in horses intended for food.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3 milligrams of dexamethasone).

(2) *Sponsor.* See No. 059130 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is given for glucocorticoid and anti-inflammatory effect in dogs and horses.

(ii) Administer intravenously as follows: Dogs—0.25 to 1 milligram initially; may be repeated for 3 to 5 days or until response is noted. Horses—2.5 to 5 milligrams. If permanent glucocorticoid effect is required, oral therapy may be substituted. When therapy is to be withdrawn after prolonged use, the daily dose should be reduced gradually over several days.

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(iv) Do not use in viral infections.
Anti-inflammatory action of

§ 522.542

21 CFR Ch. I (4-1-04 Edition)

corticosteroids may mask signs of infections. Except when used for emergency therapy, the product is contraindicated in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers.

(v) Not for use in horses intended for food.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 522.542 **Dexamethasone-21-isonicotinate suspension.**

(a) *Specifications.* Each milliliter of sterile suspension contains 1 milligram of dexamethasone-21-isonicotinate.

(b) *Sponsor.* No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.

(2) It is recommended for intramuscular administration as follows: Dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—5 to 20 milligrams. Dosage may be repeated.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition following by dystocia, fetal death, retained placenta, and metritis.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 37543, July 22, 1977, as amended at 47 FR 14703, Apr. 6, 1982]

§ 522.563 **Diatrizoate meglumine and diatrizoate sodium injection.**

(a) *Specifications.* Diatrizoate meglumine and diatrizoate sodium injection contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent dia-

trizoate meglumine and 10 percent diatrizoate sodium, in sterile aqueous solution.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs and cats for visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiology, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter into the urethra to provide desired contrasts delineation. For angiocardiology (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catheter or intraventricular puncture. For cerebral angiography rapid injection of 3 to 10 milliliters via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 1.0 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be delineated. For sialography slowly inject 0.5 to 1.0 milliliter into the duct to be delineated. For delineation of fistulous tracts slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias inject 0.5 to 1.0 milliliter per pound of body weight directly into the peritoneal cavity.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985]

§ 522.575 Diazepam injection.

(a) *Specification.* Each milliliter of sterile solution contains 5 milligrams of diazepam.

(b) *Sponsor.* See 063238 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Indications for use.* As a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia.

(2) *Dosage.* Intravenously, 0.2 milligram per kilogram of body weight 3–5 minutes before anesthesia is to be induced using a short acting barbiturate.

(3) *Limitations.* Not for use in dogs with known sensitivity to benzodiazepines. Safety in animals intended for breeding and pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 500, Jan. 6, 1993, as amended at 66 FR 46705, Sept. 7, 2001]

§ 522.650 Dihydrostreptomycin sulfate injection.

(a) *Specifications.* Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See Nos. 000069 and 055529 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Conditions of use—(1) Amount.* 5 milligrams per pound of body weight every 12 hours.

(2) *Indications for use.* Treatment of leptospirosis in dogs and horses due to *Leptospira canicola*, *L. icterohemorrhagiae*, and *L. pomona*; in cattle due to *L. pomona*; and in swine due to *L. pomona*; and *L. grippotyphosa*.

(3) *Limitations.* Administer by deep intramuscular injection only. Treatment should be continued for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination. Treatment with subtherapeutic dosages, excessive duration of therapy, or inappropriate use of this antibiotic may lead to the emergence of strepto-

mycin or dihydrostreptomycin resistant organisms. Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 522.690 Dinoprost solution.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) dinoprost.

(b) *Sponsors.* See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use—(1) Horses—(i) Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Cattle—(i) Beef cattle and nonlactating dairy heifers—(A) Amount.* 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications.* For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(ii) *Beef cattle and nonlactating dairy heifers—(A) Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of pyometra (chronic endometritis).

§ 522.723

(iii) *Nonlactating cattle*—(A) *Amount*. 25 mg as a single intramuscular injection during the first 100 days of gestation.

(B) *Indications*. For its abortifacient effect in nonlactating cattle.

(iv) *Lactating dairy cattle*—(A) *Amount*. 25 mg as a single intramuscular injection.

(B) *Indications*. For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(v) Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter may be used concurrently with progesterone intravaginal inserts as in § 529.1940 of this chapter.

(3) *Swine*—(i) *Amount*. 10 mg as a single intramuscular injection.

(ii) *Indications*. For parturition induction in swine when injected within 3 days of normal predicted farrowing.

[67 FR 41824, June 20, 2002]

§ 522.723 Diprenorphine hydrochloride injection.

(a) *Chemical name*. N-(Cyclopropylmethyl)-6,7,8,14-tetrahydro-7- α -(1-hydroxy-1-methylethyl)-6,14-endoethanonoropipavine hydrochloride.

(b) *Specifications*. Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors*. See No. 053923 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic

21 CFR Ch. I (4–1–04 Edition)

animal practice, wildlife management programs and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 60 FR 39847, Aug. 4, 1995; 64 FR 15684, Apr. 1, 1999]

§ 522.770 Doramectin.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of doramectin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.225 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount*. 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use*. For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations*. Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount*. 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use*. For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations*. Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999]

§ 522.775 Doxapram hydrochloride injection.

(a) *Specifications*. The drug is a sterile aqueous solution containing 20 milligrams doxapram hydrochloride per milliliter.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; to stimulate respiration following dystocia or caesarean section.

(2) For intravenous use in dogs and cats at a dose of 2½ to 5 milligrams of doxapram hydrochloride per pound of body weight in barbiturate anesthesia, 0.5 mg per lb. in gas anesthesia; for intravenous use in horses at 0.25 mg per lb. of body weight in barbiturate anesthesia, 0.2 mg per lb. in inhalation anesthesia, 0.25 mg per lb. with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 17838, Apr. 23, 1975, as amended at 67 FR 67521, Nov. 6, 2002]

§ 522.778 Doxycycline hyclate.

(a) *Specifications*. Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Apply subgingivally to periodontal pocket(s) of affected teeth.

(ii) *Indications for use*. For treatment and control of periodontal disease.

(iii) *Limitations*. Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with permanent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal

law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 8349, Feb. 19, 1998, as amended at 65 FR 45878, July 26, 2000]

§ 522.784 Doxylamine succinate injection.

(a) *Specifications*. Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.¹

(3) Not for use in horses intended for food.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications*. Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

§522.812

21 CFR Ch. I (4-1-04 Edition)

(i) For analgesia and tranquilization administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 64 FR 15684, Apr. 1, 1999]

§522.812 Enrofloxacin solution.

(a) *Specifications.* Each milliliter of sterile solution contains either 22.7 milligrams of enrofloxacin when intended for use in dogs or 100 milligrams of enrofloxacin when intended for use in cattle.

(b) *Sponsor.* See No. 000859 in §510.600(c) of this chapter.

(c) *Related tolerance.* See §556.228 of this chapter.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 2.5 milligrams per kilogram (1.13 milligrams per pound) of body weight as an initial dose only.

(ii) *Indications for use.* Dogs for management of diseases associated with bacteria susceptible to enrofloxacin.

(iii) *Limitations.* As a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* Single-dose therapy: 7.5 to 12.5 milligrams enrofloxacin per kilogram of body weight (3.4 to 5.7 milliliters per 100 pounds). Multiple-day therapy: 2.5 to 5.0 milligrams per kilogram of body weight (1.1 to 2.3 milliliters per 100 pounds) administered once daily for 3 to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(iii) *Limitations.* For subcutaneous use in cattle only. Do not inject more than 20 milliliters at each site. Do not slaughter within 28 days of last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. The effect of enrofloxacin on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[55 FR 26683, June 29, 1990, as amended at 62 FR 38907, July 21, 1997; 63 FR 49003, Sept. 14, 1998]

§522.820 Erythromycin injection.

(a) *Sponsor.* See 061623 in §510.600(c) of this chapter.

(b) *NAS/NRC status.* The conditions of use have been reviewed by NAS/NRC and found effective.

(c) *Dogs and cats*—(1) *Specifications.* Each milliliter of polyethylene glycol vehicle contains 100 milligrams of erythromycin base with 2 percent butyl aminobenzoate.

(2) *Conditions of use*—(i) *Amount.* 3 to 5 milligrams per pound of body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*—(A) *Dogs.* For the treatment of bacterial pneumonia,

upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

(B) *Cats*. For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

(iii) *Limitations*. Administer by deep intramuscular injection into the heavy muscles of the neck and limbs. Do not administer intravenously or intraperitoneally. Avoid subcutaneous use. Do not administer from moist or wet syringe. As with all antibiotics, appropriate *in vitro* culturing and susceptibility testing of samples taken before treatment should be conducted. Do not administer in conjunction with penicillin. As with all antibiotics, excessive continuous use may result in an overgrowth of nonsusceptible organisms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Cattle*.—(1) *Specifications*. Each milliliter of nonaqueous, buffered, alcohol base sterile solution contains 200 milligrams of erythromycin base.

(2) *Related tolerances*. See § 556.230 of this chapter.

(3) *Conditions of use*—(i) *Amount*. 4 milligrams of erythromycin base per pound of body weight once daily for up to 5 days.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations*. For intramuscular use only. Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. To avoid excess trim, do not slaughter within 21 days of last injection.

[58 FR 43795, Aug. 18, 1993, as amended at 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 522.840 Estradiol.

(a) *Specifications*. Each silicone rubber implant contains 25.7 or 43.9 milligrams of estradiol.

(b) *Sponsor*. See No. 021641 in § 510.600(c) of this chapter.

(c) *Conditions of use*. It is used for implantation in steers and heifers as follows:

(1) *Amount*. Insert one 25.7-milligram implant every 200 days; insert one 43.9-milligram implant every 400 days.

(2) *Indications for use*. For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers.

(3) *Limitations*. For subcutaneous ear implantation in steers and heifers only. A second implant may be used if desired. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-milligram implant or 400 days for the 43.9 milligram implant. Increased sexual activity (bulling, riding, and excitability) has been reported in implanted animals.

[51 FR 22276, June 19, 1986, as amended at 57 FR 41861, Sept. 14, 1992; 66 FR 56035, Nov. 6, 2001]

§ 522.841 Estradiol benzoate.

(a) *Specifications*. The product consists of a vial of estradiol benzoate microspheres and a vial of diluent.

(1) Each milliliter (mL) of constituted suspension contains 10 milligrams (mg) estradiol benzoate.

(2) Each mL of constituted suspension contains 20 mg estradiol benzoate.

(b) *Sponsor*. See No. 067210 in § 510.600(c) of this chapter.

(c) *Tolerances*. See § 556.240 of this chapter.

(d) *Conditions of use*. It is used by subcutaneous injection as follows:

(1) *Suckling beef calves*—(i) *Amount*. 10 mg; 1 mL of the product described in paragraph (a)(1) of this section.

(ii) *Indications for use*. For increased rate of weight gain.

(iii) *Limitations*. For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating

§ 522.842

21 CFR Ch. I (4-1-04 Edition)

calves. Do not use in calves to be processed for veal.

(2) *Steers fed in confinement for slaughter*—(i) *Amount*—(A) 20 mg; 1 mL of the product described in paragraph (a)(2) of this section for use in paragraph (d)(2)(ii)(A) of this section.

(B) 10 mg; 0.5 mL of the product described in paragraph (a)(2) of this section for use in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations*. For subcutaneous injection in the ear only. The use of 20 mg (1 mL) in steers does not provide additional rate of gain improvement over 10 mg (0.5 mL). Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Heifers fed in confinement for slaughter*—(i) *Amount*. One mL (20 mg) of product described in paragraph (a)(2) of this section.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations*. For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[68 FR 49704, Aug. 19, 2003]

§ 522.842 Estradiol benzoate and testosterone propionate in combination.

(a) [Reserved]

(b) *Sponsors*. See 000856 in § 510.600(c) of this chapter for use as in paragraph (d)(1)(i), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances*. See §§ 556.240 and 556.710 of this chapter.

(d) *Conditions of use—Heifers*. For implantation as follows:

(1) *Amount*. (i) 20 milligrams of estradiol benzoate and 200 milligrams of testosterone propionate per dose.

(ii) 20 milligrams estradiol benzoate and 200 milligrams testosterone propionate in eight pellets with 29 milligrams tylosin tartrate as a local antibacterial in one pellet, per implant dose.

(2) *Indications for use*. Growth promotion and improved feed efficiency.

(3) *Limitations*. For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in dairy or beef replacement heifers.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 29778, July 24, 1984; 61 FR 5506, Feb. 13, 1996; 64 FR 48294, Sept. 3, 1999]

§ 522.850 Estradiol valerate and norgestomet in combination.

(a) *Specifications*. The product is a two-component drug consisting of the following:

(1) An implant containing 6.0 milligrams of norgestomet.

(2) An injectable solution (sesame oil) containing 3.0 milligrams of norgestomet and 5.0 milligrams of estradiol valerate per 2 milliliters.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. One implant and 2 milliliters of injection at time of implantation.

(2) *Indications for use*. For synchronization of estrus/ovulation in cycling beef cattle and non-lactating dairy heifers.

(3) *Limitations*. Insert implant subcutaneously in the ear only; then immediately inject solution intramuscularly only. Counting the day of implantation as day 1, remove the implant on day 10. Collect all implants as they are removed and burn them. While animals are restrained for artificial insemination, avoid other treatments such as vaccinations, dipping, pour-on grub and louse prevention, spraying, etc. When inseminating without estrus detection, the entire treated group should be started at 48 hours after the last implant has been removed and should be completed within 6 hours. Where estrus detection is preferred, insemination should be approximately 12 hours after first detection of estrus. Those that do not conceive can be re-bred when they return to estrus approximately 17 to 25 days after implant removal. Do not use in

cows producing milk for human consumption.

[47 FR 55477, Dec. 10, 1982, as amended at 48 FR 49656, Oct. 27, 1983; 51 FR 33592, Sept. 22, 1986; 54 FR 1165, Jan. 12, 1989]

§ 522.863 Ethylisobutrazine hydrochloride injection.

(a) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 50 milligrams of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as a tranquilizer.¹

(2) It is administered intramuscularly at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight for profound tranquilization. It is administered intravenously at a dosage level of 1 to 2 milligrams of ethylisobutrazine hydrochloride per pound of body weight to effect.¹

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.883 Etorphine hydrochloride injection.

(a) *Chemical name.* 6,7,8,14 - tetrahydro - alpha - methyl - alpha - propyl - 6,14 - endo-ethenooripavine-alpha-methanol hydrochloride.

(b) *Specifications.* Each milliliter of etorphine hydrochloride injection, veterinary, contains 1 mg of etorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use.* (1) The drug is used for the immobilization of wild and exotic animals.

(2) It is administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(3) Do not use the drug unless diprenorphine hydrochloride injection, veterinary, as provided for in § 522.723, is available for use in reversing the effects of etorphine hydrochloride injection, veterinary.

(4) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 61 FR 260, Jan. 4, 1996]

§ 522.900 Euthanasia solution.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061 and 051311 for use of product described in paragraph (a)(1) of this section.

(2) No. 000856 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations.* Product labeling shall bear the following warning statements: "ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife."

(d) *Conditions of use in dogs—(1) Indications for use.* For humane, painless, and rapid euthanasia.

§ 522.914

(2) *Amount.* One mL per 10 pounds of body weight.

(3) *Limitations.* Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 42969, July 21, 2003, as amended at 68 FR 55824, Sept. 29, 2003]

§ 522.914 Fenprostalene solution.

(a) *Specifications*—(1) *Cattle.* Each milliliter of sterile solution contains 0.5 milligram of fenprostalene.

(2) *Swine.* Each milliliter of sterile solution contains 0.25 milligram of fenprostalene.

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.277 of this chapter.

(d) *Special considerations.* Labeling shall bear the following statements: Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. It is readily absorbed through the skin and may cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 1 milligram (2 milliliters) subcutaneously per animal.

(ii) *Indications for use.* For feedlot heifers to induce abortion when pregnant 150 days or less. For beef or nonlactating dairy cattle for estrus synchronization.

(iii) *Limitations.* Subcutaneous use in cattle only. Feedlot heifers to induce abortion, single dose. Beef or nonlactating dairy cattle for estrus synchronization, a single dose or two doses 11 to 13 days apart. Do not use in pregnant animals unless abortion is desired. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 0.25 milligram (1 milliliter) subcutaneously once per animal.

(ii) *Indications for use.* For sows and gilts pregnant at least 112 days for the induction of parturition.

(iii) *Limitations.* Subcutaneous use in swine only. Federal law restricts this

21 CFR Ch. I (4–1–04 Edition)

drug to use by or on the order of a licensed veterinarian.

[48 FR 7164, Feb. 18, 1983, as amended at 49 FR 26715, June 29, 1984; 54 FR 400, Jan. 6, 1989; 61 FR 5506, Feb. 13, 1996]

§ 522.940 Colloidal ferric oxide injection.

(a) *Specifications.* Each milliliter of the drug contains colloidal ferric oxide equivalent to 100 milligrams of iron stabilized with a low-viscosity dextrin and contains 0.5 percent phenol as a preservative.

(b) *NAS/NRC status.* Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(c)(1) *Sponsor.* See Nos. 017800 and 053501 in § 510.600(c) of this chapter.

(2) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 1 milliliter of the drug to each animal at any time between 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of from 1 to 2 milliliters of the drug to each animal at any time between 5 to 28 days of age.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 38938, Oct. 2, 1984; 50 FR 23298, June 3, 1985; 50 FR 25216, June 18, 1985; 51 FR 14989, Apr. 22, 1986; 51 FR 18314, May 19, 1986; 67 FR 78355, Dec. 24, 2002]

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) of florfenicol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 20 mg per kilogram (/kg) of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(A) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and

Haemophilus somnus. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(B) [Reserved]

(ii) *Amount*. 40 mg/kg body weight as a single subcutaneous injection.

(A) *Indications for use*. As in paragraph (d)(1)(i)(A) of this section; for control of respiratory disease in cattle at high risk of developing BRD associated with *M. (Pasteurella) haemolytica*, *P. multocida*, and *H. somnus*.

(B) [Reserved]

(iii) *Limitations*. Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in prurminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 42383, Aug. 15, 1996, as amended at 63 FR 26981, May 15, 1998; 63 FR 41191, Aug. 3, 1998; 64 FR 5596, Feb. 4, 1999; 64 FR 9435, Feb. 26, 1999; 67 FR 6866, Feb. 14, 2002]

§ 522.960 Flumethasone implantation or injectable dosage forms.

§ 522.960a Flumethasone suspension.

(a) *Chemical name*. 6 α ,9 α -Difluoro-11 β ,17,21 - trihydroxy - 16 α - methylpregna - 1,4 - diene - 3,20 - dione.

(b) *Specifications*. Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of flumethasone, 20 milligrams of propylene glycol, 9 milligrams of benzyl alcohol (as preservative), 8 milligrams of sodium chloride, 0.02 milligram of polysorbate-80, 0.1 milligram of citric acid, and water for injection q.s.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is recommended in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpalis, and osselets.

(2) The drug is administered intraarticularly at a dosage level of 6 to 10 milligrams per injection. The dosage level is dependent upon the size of the involved synovial structure and the degree of severity of the condition under treatment. The dosage is limited to a single injection per week in any one synovial structure.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally and parenterally to animals during the last trimester of pregnancy may induce the first stage of parturition and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The drug is not to be used in horses intended for slaughter for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

§ 522.960b Flumethasone acetate injection.

(a) *Chemical name*. 6-alpha,9-alpha-difluoro - 16 - alpha - methylprednisolone 21-acetate.

(b) *Specifications*. Flumethasone injection is sterile and contains per cubic centimeter: 2 milligrams of flumethasone acetate; 20 milligrams of propylene glycol; 9 milligrams of benzyl alcohol (as preservative); 8 milligrams of sodium chloride; 1 milligram of polysorbate 80; 0.1 milligram of citric acid; water for injection q.s.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is recommended in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(2) The drug is administered intramuscularly at the following recommended daily dosage:

Weight of animal in pounds	Dosage in milligrams
Up to 10	1.0
10 to 25	2.0
25 and over	4.0

Dosage should be adjusted according to the weight of the animal, the severity

§ 522.960c

21 CFR Ch. I (4–1–04 Edition)

of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 milligram per animal.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 0.5 milligram flumethasone.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* 1.25 to 2.5 milligrams daily, intravenously, intramuscularly, or intra-articularly.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpalis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *Limitations*—(a) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(b) When a long-term therapy is used, the dose should be individually adjusted to the minimum maintenance dose. A protein-rich diet is useful in dogs and cats on long-term therapy to counteract nitrogen loss if it should occur. A small amount of potassium chloride daily in the diet will counteract excessive potassium loss if this is present.

(c) It has been demonstrated that corticosteroids, especially at high dose levels, may result in delayed wound and fracture healing.

(d) Flumethasone may be administered to animals with bacterial diseases provided appropriate anti-

bacterial therapy is administered simultaneously.

(e) The drug is not to be used in horses intended for slaughter for food purposes.

(f) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* 0.0625 to 0.25 milligram daily, intravenously, intramuscularly, or subcutaneously; 0.125 to 1.0 milligram daily, intralesionally, depending on the size and location of the lesion; 0.166 to 1.0 milligram daily, intra-articularly, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* It is used for the treatment of musculoskeletal conditions due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

(3) *Cats*—(i) *Amount.* 0.03125 to 0.125 milligram daily intravenously, intramuscularly, or subcutaneously.

(ii) *Indications for use.* It is used for the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

[44 FR 16011, Mar. 16, 1978, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.970 Flunixin meglumine solution.

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See Nos. 000061, 055529, and 059130 for use as in paragraph (e) of this section.

(2) See Nos. 000856 and 057561 for use as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 0.5 mg per pound (lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Beef cattle and nonlactating dairy cattle*— (i) *Amount.* 1.1 to 2.2 mg/kilogram (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into 2 doses administered at 12-hour intervals, intravenously, for up to 3 days.

(ii) *Indications for use.* For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. Not for use in lactating or dry dairy cows. A withdrawal period has not been established for use in premerinating calves. Do not use in calves to be processed for veal.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998; 67 FR 9400, Mar. 1, 2002; 68 FR 70701, Dec. 19, 2003]

§ 522.995 Fluprostenol sodium injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains fluprostenol sodium equivalent to 50 micrograms of fluprostenol.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 0.55 microgram fluprostenol per kilogram of body weight.

(2) *Indications for use.* The drug is used in mares for its luteolytic effect to control the timing of estrus in es-

trous cycling and in clinically anestrous mares that have a corpus luteum.

(3) *Limitations.* Administer by intramuscular injection only. *Warning:* Not for use in horses intended for food. For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Fluprostenol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

[44 FR 52191, Sept. 7, 1979, as amended at 47 FR 22092, May 21, 1982]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications.* Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor.* See 059521 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use.* For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations.* For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

§ 522.1004

21 CFR Ch. I (4–1–04 Edition)

(2) *Sponsor*. See 063112 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use*. The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations*. Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997]

§ 522.1004 Fomepizole.

(a) *Specifications*. Two vials, one containing 1.5 grams fomepizole (1.5 milliliter of 1.0 gram fomepizole per milliliter sterile aqueous solution), and one vial containing 30 milliliters of 0.9 percent sodium chloride injection USP (as a diluent).

(b) *Sponsor*. See 062161 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 20 milligrams per kilogram initially, 15 milligrams per kilogram at 12 and 24 hours, and 5 milligrams per kilogram at 36 hours.

(2) *Indications for use*. As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.

(3) *Limitations*. Administer intravenously. For use by or on the order of a licensed veterinarian.

[61 FR 68147, Dec. 27, 1996]

§ 522.1010 Furosemide.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of furosemide diethanolamine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000010 for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 061623 for use as in paragraph (d)(2)(ii) of this section.

(3) Nos. 057926 and 059130 for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 1.25 to 2.5 mg per pound (lb) body weight once or twice daily, intramuscularly or intravenously.

(ii) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(2) *Horses*—(i) *Amount*. 250 to 500 mg per animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(ii) *Amount*. 0.5 mg/lb body weight once or twice daily, intramuscularly or intravenously.

(A) *Indications for use*. For treatment of acute noninflammatory tissue edema.

(B) *Limitations*. Do not use in horses intended for food.

(3) *Cattle*—(i) *Amount*. 500 mg/animal once daily, intramuscularly or intravenously; or 250 mg/animal twice daily at 12-hour intervals, intramuscularly or intravenously.

(ii) *Indications for use*. For the treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations*. Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

[66 FR 47961, Sept. 17, 2001, as amended at 67 FR 18086, Apr. 15, 2002; 68 FR 59881, Oct. 20, 2003]

§ 522.1020 Gelatin solution.

(a) *Specifications*. It is sterile and each 100 cubic centimeters contains 8 grams of gelatin in an 0.85 percent sodium chloride solution.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used to restore circulatory volume and maintain blood pressure in animals being treated for shock.

(2) The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight. It is administered intravenously at a rate of 10 cubic centimeters per minute in small animals and 20 to 30 cubic centimeters per minute in large animals. The solution is administered aseptically and must be between 50 to 70 °F. when injected.

(3) A few animals will exhibit signs of allergic reaction. This solution can cause transient reversible nephrosis. This product is not intended to replace whole blood in cases of anemia and should not be used in the presence of renal dysfunction. Unused portions remaining in bottles should be discarded.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.1044 Gentamicin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to either 5, 50, or 100 milligrams of gentamicin.

(b) *Sponsors.* (1) See No. 000061 in § 510.600(c) of this chapter for use of: 5-milligrams-per-milliliter solution in swine as in paragraph (d)(4) of this section, 50-milligrams-per-milliliter solution in dogs and cats as in paragraph (d)(1) of this section, 50- and 100-milligrams-per-milliliter solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) [Reserved]

(3) See No. 000010 for use of 50 milligrams-per-milliliter solution in dogs as in paragraph (d)(5) of this section.

(4) See No. 059130 for use of 100 milligram-per-milliliter solution in turkeys as in paragraph (d)(2) of this section and in chickens as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use—(1) Dogs and cats—(i) Amount.* Two milligrams of gentamicin per pound of body weight, twice daily on the first day, once daily thereafter, using a 50 milligram-per-milliliter solution.

(ii) *Indications for use—(a) Dogs.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (tonsillitis, pneumonia, tracheobronchitis), skin and soft tissue (pyodermatitis, wounds, lacerations, peritonitis).

(b) *Cats.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (pneumonitis, pneumonia, upper respiratory tract infections), skin and soft tissue (wounds, lacerations, peritonitis), and as supportive therapy for secondary bacterial infections associated with panleucopenia.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If response is not noted after 7 days, the antibiotic sensitivity of the infecting organism should be retested. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys—(i) Amount.* One milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 5 milligrams-per-milliliter.

(ii) *Indications for use.* As an aid in the prevention of early mortality due to Arizona paracolon infections susceptible to gentamicin.

(iii) *Limitations.* For 1- to 3-day old turkey poults. Administer subcutaneously in the neck. Injected poults must not be slaughtered for food for at least 9 weeks after treatment.

(3) *Chickens—(i) Amount.* 0.2 milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 1.0 milligram-per-milliliter.

(ii) *Indications for use.* In day-old chickens, for prevention of early mortality caused by *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* that are susceptible to gentamicin.

§ 522.1055

(iii) *Limitations.* For use in day-old chickens only. Administer aseptically, injecting the diluted product subcutaneously in the neck. Do not slaughter treated animals for food for at least 5 weeks after treatment.

(4) *Swine*—(i) *Amount.* 5 milligrams of gentamicin as a single intramuscular dose using 5 milligram-per-milliliter solution.

(ii) *Indications for use.* In piglets up to 3 days old for treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(iii) *Limitations.* For single intramuscular dose in pigs up to 3 days of age only. Do not slaughter treated animals for food for at least 40 days following treatment.

(5) *Dogs*—(i) *Amount.* 2 milligrams of gentamicin per pound of body weight, twice daily on the first day, then once daily.

(ii) *Indications for use.* For use in the treatment of urinary tract infections (cystitis) caused by *Proteus mirabilis*, *Escherichia coli*, and *Staphylococcus aureus*.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If no improvement is seen after 3 days, treatment should be discontinued and the diagnosis reevaluated. Treatment not to exceed 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 1942, Jan. 13, 1978, as amended at 48 FR 791, Jan. 7, 1983; 51 FR 15606, Apr. 25, 1986; 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 60 FR 29985, June 7, 1995; 61 FR 24441, May 15, 1996; 62 FR 45157, Aug. 26, 1997; 63 FR 59714, Nov. 5, 1998; 63 FR 68182, Dec. 10, 1998; 65 FR 45877, July 26, 2000]

§ 522.1055 Gleptoferron injection.

(a) *Specifications.* Each milliliter contains the equivalent of 200 milligrams of elemental iron as gleptoferron (complex of ferric hydroxide and dextran glucoheptonic acid), and 0.5 percent phenol as a preservative.

(b) *Sponsor.* See 062408 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in baby pigs as follows:

(1) For prevention of iron deficiency anemia, administer 200 milligrams of elemental iron intramuscularly on or before 3 days of age.

21 CFR Ch. I (4–1–04 Edition)

(2) For treatment of iron deficiency anemia, administer 200 milligrams of elemental iron intramuscularly.

[45 FR 61288, Sept. 16, 1980, as amended at 61 FR 18672, Apr. 29, 1996]

§ 522.1066 Glycopyrrolate injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 0.2 milligram of glycopyrrolate.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated as a preanesthetic agent in dogs and cats.

(2) It is administered intravenously, intramuscularly, or subcutaneously in dogs and intramuscularly in cats at a dosage level of 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight).

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 21567, May 13, 1983, as amended at 67 FR 67521, Nov. 6, 2002]

§ 522.1077 Gonadorelin injectable.

(a) *Specifications.* Each milliliter sterile aqueous solution contains 50 micrograms of gonadorelin (as hydrochloride).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* 100 micrograms per cow intramuscularly.

(2) *Indications for use.* For the treatment of cystic ovaries (ovarian follicular cysts) in cattle to reduce the time to first estrus.

(3) *Limitations.* For intramuscular use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50235, Dec. 5, 1989]

§ 522.1078 Gonadorelin diacetate tetrahydrate.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (µg) of gonadorelin diacetate tetrahydrate.

(b) *Sponsors.* See Nos. 050604, 057926, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle.* It is used as follows:

(1) *Amount.* 100 µg per cow as a single intramuscular or intravenous injection.

(2) *Indications for use.* For the treatment of ovarian cysts in dairy cattle.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 68759, Nov. 13, 2002]

§ 522.1079 Serum gonadotropin and chorionic gonadotropin.

(a) *Specifications.* Each dose consists of 400 international units (I.U.) serum gonadotropin and 200 I.U. chorionic gonadotropin as a freeze-dried powder to be reconstituted with 5 milliliters of sterile aqueous diluent.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine.* (1) *Amount.* 400 I.U. serum gonadotropin with 200 I.U. chorionic gonadotropin per 5 milliliters dose per animal.

(2) *Indications for use.* (i) *Gilts.* For induction of fertile estrus (heat) in healthy prepuberal (noncycling) gilts.

(ii) *Sows.* For induction of estrus in healthy weaned sows experiencing delayed return to estrus.

(3) *Limitations.* For subcutaneous use only.

(i) *Gilts.* For use only in gilts over 5 1/2 months of age and weighing at least 85 kilograms (187 pounds).

(ii) *Sows.* Delayed return to estrus is most prevalent after the first litter. The effectiveness has not been established after later litters. Delayed return to estrus often occurs during periods of adverse environmental conditions, and sows mated under such conditions may farrow smaller than normal litters.

[55 FR 1405, Jan. 16, 1990, as amended at 58 FR 52222, Oct. 7, 1993]

§ 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.

(a)(1) *Specifications.* Chorionic gonadotropin for injection is supplied in vials containing 5,000, 10,000 or 20,000 U.S.P. units of lyophilized powder for reconstitution with the accompanying sterile diluent to a 10 milliliter solution.

(2) *Sponsor.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(i) Nos. 000402 and 053501 for use of 10,000 U.S.P. units intramuscularly, 2,500 to 5,000 U.S.P. units intravenously, and 500 to 2,500 U.S.P. units intrafollicularly in cattle.

(ii) Nos. 058639 and 063323 for use of 10,000 U.S.P. units intramuscularly and 500 to 2,500 U.S.P. units intrafollicularly in cattle.

(iii) No. 057926 for use of 10,000 U.S.P. units intramuscularly in cattle and finfish.

(3) *Related tolerances.* See § 556.304 of this chapter.

(4) *Conditions of use in cattle*—(i) *Amount.* 10,000 USP units as a single, deep intramuscular injection; 500 to 2,500 USP units for intrafollicular injection; 2,500 to 5,000 USP units intravenously.

(b) 500 to 2,500 U.S.P. units for intrafollicular injection.

(c) 2,500 to 5,000 U.S.P. units intravenously.

(ii) *Indications for use.* For parenteral use in cows for treatment of nymphomania (frequent or constant heat) due to cystic ovaries.

(iii) *Limitations.* Dosage may be repeated in 14 days if the animal's behavior or rectal examination of the ovaries indicates the necessity for retreatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Conditions of use in finfish*—(i) *Amount.* 50 to 510 I.U. per pound of body weight for males, 67 to 1816 I.U. per pound of body weight for females, by intramuscular injection.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* May administer up to three doses. The total dose administered per fish (all injections combined) should not exceed 25,000 I.U. chorionic gonadotropin (25 milliliters) in fish intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) [Reserved]

[42 FR 58167, Nov. 8, 1977, as amended at 45 FR 81038, Dec. 9, 1980; 50 FR 41489, Oct. 11, 1985; 50 FR 45603, Nov. 1, 1985; 52 FR 25212, July 6, 1987; 56 FR 67175, Dec. 30, 1991; 56 FR 14642, Apr. 11, 1991; 63 FR 51822, Sept. 29, 1998; 64 FR 48544, Sept. 7, 1999; 66 FR 22117, May 3, 2001]

§ 522.1085

21 CFR Ch. I (4–1–04 Edition)

§ 522.1085 **Guaifenesin sterile powder.**

(a) *Specifications.* It is a sterile powder containing guaifenesin.

(b) *Sponsor.* See Nos. 000856 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for intravenous use as a muscle relaxant in horses.

(2) A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution. It is administered by rapid intravenous infusion at a fixed dosage of 1 milliliter of prepared solution per pound of body weight.

(3) Not to be used in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 48039, Dec. 10, 1984, as amended at 60 FR 27223, May 23, 1995; 67 FR 67521, Nov. 6, 2002]

§ 522.1086 **Guaifenesin injection.**

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of guaifenesin and 50 milligrams of dextrose.

(b) *Sponsor.* See Nos. 037990 and 059130 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) The drug is used intravenously in horses as a skeletal muscle relaxant.

(2) Administer rapidly at a dosage of 1 milliliter per pound of body weight.

(3) No to be used in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 27223, May 23, 1995, as amended at 63 FR 29352, May 29, 1998]

§ 522.1125 **Hemoglobin glutamer-200 (bovine).**

(a) *Specifications.* Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solution. It is a sterile, clear, dark purple solution.

(b) *Sponsor.* See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* One-time dose of 10 to 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use.* For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) *Limitations.* For intravenous use only. Overdosage or an excessive rate of administration (greater than 10 milliliters per kilogram per hour) may result in circulatory overload. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 11598, Mar. 10, 1998, as amended at 65 FR 20732, Apr. 18, 2000]

§ 522.1145 **Hyaluronate sodium injection.**

(a)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000009 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—20 milligrams; larger joint (hock)—40 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 053501 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—10 milligrams; larger joint (hock)—20 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular injection in horses only. Treatment

may be repeated at weekly intervals for a total of four treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* Small and medium-size joints (carpal, fetlock)—20 milligrams.

(ii) *Indications for use.* Treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular injection in horses only. Treatment may be repeated after 1 or more weeks but not to exceed 2 injections per week for a total of 4 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* 50 milligrams in carpal and fetlock joints.

(ii) *Indications for use.* For treatment of equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

(iii) *Limitations.* For intraarticular injection in horses only. Not for use in horses intended for food. Not intended for use in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 000859 in § 510.600(c)(2) of this chapter.

(3) *Conditions of use—(i) Amount.* Intraarticular: 20 milligrams in the carpus or fetlock. Intravenous: 40 milligrams slowly into the jugular vein.

(ii) *Indications for use.* Treatment of carpal or fetlock joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intraarticular or intravenous use in horses only. Treat-

ment may be repeated at weekly intervals for a total of three treatments. Not for use in horses intended for food. The safety of use of this drug in breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(f)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 060865 in § 510.600(c).

(3) *Conditions of use—(i) Amount.* Small and medium-size joints (carpal, fetlock)—22 milligrams; larger joint (hock)—44 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 45124, Nov. 15, 1984, as amended at 51 FR 11438, Apr. 3, 1986; 51 FR 25032, July 10, 1986; 53 FR 19773, May 31, 1988; 53 FR 22297, June 15, 1988; 56 FR 50814, Oct. 9, 1991; 57 FR 2837, Jan. 24, 1992; 59 FR 33198, June 28, 1994; 61 FR 59003, Nov. 20, 1996; 63 FR 59216, Nov. 3, 1998]

§ 522.1150 Hydrochlorothiazide injection.

(a) *Specifications.* Each milliliter contains 25 milligrams of hydrochlorothiazide.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 5 to 10 milliliters (125 to 250 milligrams) intravenously or intramuscularly once or twice a day. After onset of diuresis, treatment may be continued with an orally administered maintenance dose.

(2) *Indications for use.* For use in cattle as an aid in the treatment of postparturient udder edema.¹

(3) *Limitations.* Animals should be regularly and carefully observed for

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 522.1155

early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. Milk taken from dairy animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[43 FR 59058, Dec. 19, 1978, as amended at 62 FR 63271, Nov. 28, 1997]

§ 522.1155 Imidocarb dipropionate sterile powder.

(a) *Specifications.* Imidocarb dipropionate powder is reconstituted with sterile water. Each milliliter of solution contains 100 milligrams of imidocarb base.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* The drug is used in horses and zebras as follows:

(1) *Amount.* For *Babesia caballi* infections, use intramuscularly 2 milligrams of imidocarb base per kilogram of body weight, repeating dosage once after 24 hours. For *Babesia equi* infections, use 4 milligrams of imidocarb base per kilogram of body weight, repeating dosage four times at 72-hour intervals.

(2) *Indications for use.* For the treatment of babesiosis (piroplasmosis) caused by *Babesia caballi* and *Babesia equi*.

(3) *Limitations.* Administer intramuscularly in the neck region. Do not inject intravenously. Do not use for other equidae or for animals of other species. Do not use in horses less than 1 year old. Do not use for animals in near-term pregnancies. Imidocarb dipropionate is a cholinesterase inhibitor. Do not use this product simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, APHIS, USDA, to

21 CFR Ch. I (4-1-04 Edition)

licensed or full-time State, Federal, or military veterinarians.

[43 FR 40455, Sept. 12, 1978, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.1156 Imidocarb dipropionate solution.

(a) *Specifications.* Each milliliter of injectable solution contains 120 milligrams of imidocarb.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) *Indications for use.* Treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(iii) *Limitations.* Use subcutaneously or intramuscularly. Not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments. Imidocarb is a cholinesterase inhibitor. Do not use simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 66984, Dec. 23, 1997]

§ 522.1182 Iron dextran complex injection.

(a)(1) *Specifications.* Each milliliter of sterile solution contains ferric hydroxide dextran complex equivalent to 100 milligrams of elemental iron. It contains 0.5 percent phenol as a preservative.

(2) [Reserved]

(3)(i) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(ii) *Conditions of use.* It is used in baby pigs as follows:

(a) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(b) For the treatment of anemia due to iron deficiency, administer and

intramuscular injection of 200 milligrams of elemental iron.

(4)(i) *Sponsor*. See Nos. 000061 and 062408 in § 510.600(c) of this chapter.

(ii) *Conditions of use*. It is used in baby pigs as follows:

(a) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 milligrams of elemental iron to animals from 1 to 3 days of age.

(b) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 milligrams of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(b)(1) *Specifications*. Each milliliter of sterile solution contains ferric hydroxide in complex with dextran equivalent to 200 milligrams of elemental iron. It contains 0.5 percent phenol as a preservative.

(2)(i) *Sponsor*. See Nos. 000010 and 059130 in § 510.600(c) of this chapter.

(ii) *Conditions of use*. It is used in baby pigs as follows:

(a) For prevention of baby pig anemia due to iron deficiency, intramuscularly inject 200 milligrams of elemental iron (1 milliliter) at 1 to 3 days of age.

(b) For treatment of baby pig anemia due to iron deficiency, intramuscularly inject 200 milligrams of elemental iron at the first sign of anemia.

[49 FR 38938, Oct. 2, 1984, as amended 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 61 FR 18672, Apr. 29, 1996; 62 FR 35076, June 30, 1997; 63 FR 53578, Oct. 6, 1998]

§ 522.1183 Iron hydrogenated dextran injection.

(a) *Specifications*. Each milliliter contains 100 milligrams of elemental iron stabilized with a low molecular weight hydrogenated dextran and 0.5 percent phenol as a preservative.

(b)-(c) [Reserved]

(d)(1) *Sponsor*. See No. 000003 in § 510.600(c) of this chapter.

(2) *Conditions of use*. It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron in baby pigs up to 4 weeks of age.

(e)(1) *Sponsors*. See Nos. 000010, 017287, and 059130 in § 510.600(c) of this chapter.

(2) *Conditions of use*. It is used in baby pigs as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly 100 milligrams at 2 to 4 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly 100 milligrams. Treatment may be repeated in 10 days.

[42 FR 53955, Oct. 4, 1977, as amended at 46 FR 39128, July 31, 1981; 50 FR 23298, June 3, 1985; 52 FR 18691, May 19, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 40728 and 40729, Oct. 18, 1988; 55 FR 8462, Mar. 8, 1990; 55 FR 33670, Aug. 17, 1990; 62 FR 35076, June 30, 1997; 63 FR 44384, Aug. 19, 1998; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001]

§ 522.1192 Ivermectin injection.

(a) *Specifications*—(1) *Horses*. Each milliliter of sterile aqueous solution contains 20 milligrams of ivermectin (2 percent).

(2) *Cattle, reindeer, swine, and American bison*. Each milliliter of sterile aqueous solution contains 10 milligrams of ivermectin (1 percent).

(3) *Piglets 70 pounds or less and ranch-raised foxes*. Each milliliter of sterile aqueous solution contains 2.7 milligrams of ivermectin (0.27 percent).

(b) *Sponsors*. See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See No. 059130 in § 510.600(c) of this chapter for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 20 milligrams per 100 kilograms (220 pounds) of body weight.

(ii) *Indications for use*. It is used in horses for the treatment and control of large strongyles (adult) (*Strongylus vulgaris*, *Strongylus edentatus*, *Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris*

equorum), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (*microfilariae*) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

(iii) *Limitations.* For intramuscular use only. Do not use intravenously. Not for use in horses intended for food. Effects of this drug on pregnant mares have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 10 milligrams per 50 kilograms (110 pounds) body weight (200 micrograms per kilogram).

(ii) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* for 28 days after treatment, and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *Oesophagostomum radiatum* for 14 days after treatment.

(iii) *Limitations.* For subcutaneous use only. Not for intramuscular use. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Reindeer*—(i) *Amount.* 10 milligrams per 50 kilograms (110 pounds) body weight.

(ii) *Indications for use.* It is used in reindeer for treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations.* For subcutaneous use only. Not for intramuscular use. Do not treat reindeer within 56 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Swine*—(i) *Amount.* 300 micrograms per kilogram (2.2 pounds).

(ii) *Indications for use.* It is used in swine for treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostromylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *Strongyloides ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*Haematopinus suis*); and mites (*Sarcoptes scabiei* var. *suis*).

(iii) *Limitations.* For subcutaneous injection in the neck of swine only. Do not treat swine within 18 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(5) *Ranch-raised foxes*—(i) *Amount.* 200 micrograms per kilogram body weight. Repeat in 3 weeks.

(ii) *Indications for use.* For treatment and control of ear mites (*Otodectes cynotis*).

(iii) *Limitations.* For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(6) *American bison*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) *Indications for use.* It is used in American bison for the treatment and control of grubs (*Hypoderma bovis*).

(iii) *Limitations.* For subcutaneous use. Do not slaughter within 56 days of

last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 5344, Feb. 13, 1984, as amended at 50 FR 30268, July 25, 1985; 51 FR 25686, July 16, 1986; 51 FR 27021, July 29, 1986; 51 FR 29463, Aug. 18, 1986; 53 FR 11064, Apr. 5, 1988; 56 FR 14020, Apr. 5, 1991; 60 FR 45041, Aug. 30, 1995; 62 FR 14634, Mar. 27, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 7702, Feb. 17, 1998; 64 FR 26671, May 17, 1999; 66 FR 13236, Mar. 5, 2001]

§ 522.1193 Ivermectin and clorsulon injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams (1 percent) of ivermectin and 100 milligrams (10 percent) of clorsulon.

(b) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.163 and 556.344 of this chapter.

(d) *Conditions of use*—(1) *Amount.* 1 milliliter (10 milligrams of ivermectin and 100 milligrams of clorsulon) per 50 kilograms (110 pounds).

(2) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*; lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* for 28 days after treatment, *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

(3) *Limitations.* For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in

other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[55 FR 38984, Sept. 24, 1990, as amended at 62 FR 14302, Mar. 26, 1997; 62 FR 63271, Nov. 28, 1997; 64 FR 26671, May 17, 1999]

§ 522.1204 Kanamycin sulfate injection.

(a) *Specifications.* Each milliliter of kanamycin sulfate injection veterinary contains either 50 or 200 milligrams of kanamycin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in the treatment of bacterial infections due to kanamycin sensitive organisms in dogs and cats.

(2) It is administered subcutaneously or intramuscularly at 5 milligrams per pound of body weight per day in equally divided doses at 12-hour intervals.

(3) Its label shall bear an appropriate expiration date.

(4) Restricted to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 64 FR 403, Jan. 5, 1999]

§ 522.1222 Ketamine hydrochloride injectable dosage forms.

§ 522.1222a Ketamine.

(a) *Specifications.* Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) *Sponsors.* See Nos. 000010, 000074, 000856, 059130, 061690, 064408, and 064847 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Cats*—(i) *Amount.* 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(ii) *Indications for use.* For restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(2) *Subhuman primates*—(i) *Amount.* 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

§ 522.1222b

(ii) *Indications for use.* For restraint.

[67 FR 17283, Apr. 10, 2002]

§ 522.1222b Ketamine hydrochloride with promazine hydrochloride and aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* Ketamine hydrochloride, (±),-2-(*o*-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride, with promazine hydrochloride, 10-[3-(dimethylamino) propyl] phenothiazine monohydrochloride, and aminopentamide hydrogen sulfate.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains: Ketamine hydrochloride equivalent to 100 milligrams ketamine base activity, 7.5 milligrams of promazine hydrochloride, and 0.0625 milligram of aminopentamide hydrogen sulfate, with 1:10,000 benzethonium chloride.

(c) *Sponsor.* See Code No. 000856 in § 510.600(c) of this chapter.

(d) *Special considerations.* Store in a cool place. Protect from light. Do not use if precipitate appears.

(e) *Conditions of use.* (1) It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

(2) It is administered intramuscularly at a recommended dose from 15 to 20 milligrams ketamine base per pound of body weight, depending on the effect desired.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 59342, Dec. 23, 1975, as amended at 42 FR 3838, Jan. 21, 1977; 53 FR 27851, July 25, 1988]

§ 522.1225 Ketoprofen solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 100 milligrams of ketoprofen.

(b) *Sponsor.* See 000856 in 21 CFR 510.600(c) of this chapter.

(c) *Conditions of use in horses—*(1) *Amount.* 1.0 milligram per pound of body weight once daily for up to 5 days.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(3) *Limitations.* For intravenous use only. Do not use in breeding animals.

21 CFR Ch. I (4–1–04 Edition)

Effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 40653, Oct. 4, 1990]

§ 522.1228 [Reserved]

§ 522.1244 Levamisole phosphate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600 of this chapter for use of 13.65 percent injection, and see No. 053501 for use of 13.65 and 18.2 percent injection.

(c) *Conditions of use—*(1) *Amount.* 2 milliliters per 100 pounds of body weight, subcutaneously in the neck.

(2) *Indications for use.* (i) The 13.65 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(ii) The 18.2 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) and lungworms (*Dictyocaulus*).

(3) *Limitations.* Do not administer more than 10 milliliters per site. Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian before using in severely debilitated animals or animals under severe stress. Do not administer to cattle within 7 days of

slaughter. Do not administer to dairy animals of breeding age.

[43 FR 20489, May 12, 1978, as amended at 43 FR 29289, July 7, 1978; 43 FR 60895, Dec. 29, 1978; 47 FR 10807, Mar. 12, 1982; 62 FR 61625, Nov. 19, 1997; 65 FR 61090, Oct. 16, 2000; 67 FR 63055, Oct. 10, 2002]

§ 522.1260 Lincomycin.

(a) *Specifications.* Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to:

(1) 25, 50, 100, or 300 milligrams (mg) lincomycin.

(2) 25, 100, or 300 mg lincomycin.

(3) 300 mg lincomycin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section.

(1) No. 000009 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e) of this section.

(2) Nos. 000857 and 059130 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 046573 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(2) of this section.

(c) *Special considerations.* When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to the labeling requirements of § 201.105 of this chapter.

(d) *Related tolerances.* See § 556.360 of this chapter.

(e) *Conditions of use.* It is used for animals as follows:

(1) *Dogs and cats*—(i) *Amount.* 5 mg per pound (lb) of body weight twice daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.

(ii) *Indications for use.* Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.

(ii) *Indications for use.* Treatment of infectious arthritis and mycoplasma pneumonia.

(iii) *Limitations.* Do not treat within 48 hours of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985; 67 FR 34388, May 14, 2002; 68 FR 51705, Aug. 28, 2003; 69 FR 11507, Mar. 11, 2004]

§ 522.1289 Lufenuron suspension.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 milligrams of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Cats*—(i) *Amount.* 10 milligrams per kilogram (4.5 milligrams per pound) of body weight every 6 months, subcutaneously.

(ii) *Indications for use.* For use in cats 6 weeks of age and older, for control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(iii) *Limitations.* For subcutaneous use in cats only. The safety of this product in reproducing animals has not been established. Do not use in dogs. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 29552, June 1, 1998]

§ 522.1290 Luprostitol sterile solution.

(a) *Specifications.* Each milliliter of sterile solution contains 7.5 milligrams of luprostitol.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following statements: *Warning:* Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Luprostitol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

§ 522.1335

(d) *Conditions of use*—(1) *Amount*. 7.5 milligrams per mare.

(2) *Indications for use*. The drug is used in mares for estrus control and termination of pregnancy.

(3) *Limitations*. Administer by intramuscular injection only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 1185, Jan. 12, 1990, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 61 FR 66582, Dec. 18, 1996]

§ 522.1335 **Medetomidine hydrochloride injection.**

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) *Sponsor*. See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use*. As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations*. Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severely debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996]

§ 522.1350 **Melatonin implant.**

(a) *Specifications*. The drug is a silicone rubber elastomer implant containing 2.7 milligrams of melatonin.

(b) *Sponsor*. See No. 053923 in § 510.600(c) of this chapter.

21 CFR Ch. I (4-1-04 Edition)

(c) *Conditions of use*—(1) *Amount*. One implant per mink.

(2) *Indications for use*. For use in healthy male and female kit and adult female mink (*Mustela vison*) to accelerate the fur priming cycle.

(3) *Limitations*. For subcutaneous implantation in mink only. Do not implant potential breeding stock. Do not use in food-producing animals.

[59 FR 37422, July 22, 1994]

§ 522.1362 **Melarsomine dihydrochloride for injection.**

(a) *Specifications*. The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications*. Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L₅) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations*. Administer only by deep intramuscular injection in the lumbar muscles (L₃-L₅). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Syndrome). Not for use in breeding animals and lactating

Food and Drug Administration, HHS

§ 522.1410

or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995]

§ 522.1367 Meloxicam.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 0.2 mg/kilogram (kg) body weight by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.1 mg/kg body weight once daily as in § 520.1350(c) of this chapter.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 68724, Dec. 10, 2003]

§ 522.1372 Mepivacaine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 20 milligrams of mepivacaine hydrochloride.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use in horses as a local anesthetic for infiltration, nerve block, intra-articular and epidural anesthesia and topical and/or infiltration anesthesia of the laryngeal mucosa prior to ventriculectomy.

(2) It is administered as follows: for nerve block, 3 to 15 milliliters; for epidural anesthesia, 5 to 20 milliliters; for intra-articular anesthesia, 10 to 15 milliliters; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to ventriculectomy, by topical spray, 25 to 40 milliliters, by infiltration, 20 to 50 milliliters.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 5349, Jan. 28, 1977, as amended at 42 FR 36995, July 19, 1977; 55 FR 23076, June 6, 1990]

§ 522.1380 Methocarbamol injection.

(a) *Specifications.* The product is a sterile, pyrogen-free solution, each milliliter containing 100 milligrams of methocarbamol, 0.5 milliliter of polyethylene glycol 300, and water for injection q.s. Its pH is 3.5 to 6.0.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Dogs and cats.* 20 milligrams per pound of body weight for moderate conditions, 25 to 100 milligrams per pound of body weight for severe conditions (tetanus and strychnine poisoning), total cumulative dose not to exceed 150 milligrams per pound of body weight.

(ii) *Horses.* 2 to 10 milligrams per pound of body weight for moderate conditions, 10 to 25 milligrams per pound of body weight for severe conditions (tetanus), additional amounts may be needed to relieve residual effects and to prevent recurrence of symptoms.

(2) *Indications for use.* As an adjunct for treating acute inflammatory and traumatic conditions of the skeletal muscles and to reduce muscular spasms.

(3) *Limitations.* For intravenous use only. For dogs, administer rapidly half the estimated dose, pause until the animal starts to relax, then continue administration to effect. For horses, administer rapidly to effect. Not for horses intended for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 79758, Dec. 2, 1980, as amended at 46 FR 18964, Mar. 27, 1981; 67 FR 67521, Nov. 6, 2002]

§ 522.1410 Sterile methylprednisolone acetate suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains 20 or 40 milligrams of methylprednisolone acetate.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these

Continued

§ 522.1451

21 CFR Ch. I (4-1-04 Edition)

(b) *Sponsors.* See Nos. 000009 and 000010 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone acetate, as with other corticoids, is contraindicated in animals with arrested tuberculosis, peptic ulcer, and Cushing's syndrome. The presence of active tuberculosis, diabetes mellitus, osteoporosis, renal insufficiency, predisposition to thrombophlebitis, hypertension, or congestive heart failure necessitates carefully controlled use of corticosteroids. Intrasyovial, intratendinous, or other injections of corticosteroids for local effect are contraindicated in the presence of acute infectious conditions. Exacerbation of pain, further loss of joint motion, with fever and malaise following injection may indicate that the condition has become septic. Appropriate antibacterial therapy should be instituted immediately.

(d) *Conditions of use—(1) Amount—(i) Intramuscular.* Dosage may be repeated when necessary, as follows: dogs—2 to 40 milligrams (up to 120 milligrams in extremely large breeds or dogs with severe involvement); cats—10 to 20 milligrams; horses—200 milligrams.¹

(ii) *Intrasyovial.* Dosage may be repeated when necessary, as follows: horses—40 to 240 milligrams; dogs—up to 20 milligrams.¹

(2) *Indications for use.* Treatment of inflammation and related disorders in dogs, cats, and horses;¹ treatment of allergic and dermatologic disorders in dogs and cats; and as supportive therapy to antibacterial treatment of severe infections in dogs and cats.

(3) *Limitations.* Not for use in horses intended for food. Not for human use.

¹uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 59058, Dec. 19, 1978, as amended at 51 FR 741, Jan. 8, 1986; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 522.1451 Moxidectin.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs—(1) Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) and *Uncinaria stenocephala* infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002]

§ 522.1452 Nalorphine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 5 milligrams of nalorphine hydrochloride.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) *Indications for use.* Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations.* Successive doses of the drug gradually lose their analeptic effect and eventually induce respiratory depression equal to that of opiates. Therefore, do not exceed therapeutic dosage. Do not mix drug with

mepiridine solutions because the buffer will cause precipitation. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997]

§ 522.1462 Naloxone hydrochloride injection.

(a) *Specifications.* Naloxone hydrochloride injection is an aqueous sterile solution containing 0.4 milligram of naloxone hydrochloride per milliliter.

(b) *Sponsor.* See No. 060951 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as a narcotic antagonist in dogs.

(2) It is administered by intravenous, intramuscular, or subcutaneous injection at an initial dose of 0.04 milligram per kilogram of body weight. When given intravenously, the dosage may be repeated at 2- to 3-minute intervals as necessary. Onset of action by intramuscular or subcutaneous injection is slightly longer than it is by intravenous injection, and repeated dosages must be administered accordingly.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 47 FR 20757, May 14, 1982; 54 FR 32632, Aug. 9, 1989; 63 FR 7701, Feb. 17, 1998]

§ 522.1465 Naltrexone hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use in elk and moose—*

(1) *Amount.* 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use.* As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations.* Available data are inadequate to recommend use in pregnant animals. Avoid using during breeding season. Do not use in domestic food-producing animals. Do not use

in free-ranging animals for 45 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 5320, Feb. 5, 1997]

§ 522.1468 Naproxen for injection.

(a) *Specifications.* The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses.* (1) *Dosage.* Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996]

§ 522.1484 Neomycin sulfate sterile solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of neomycin sulfate (equivalent to 35 milligrams of neomycin base).¹

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* 5 milligrams per pound of body weight daily divided into portions administered every 6 to 8 hours for 3 to 5 days.¹

(2) *Indications for use.* Administer to dogs and cats for the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.¹

¹These claims are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

§ 522.1503

21 CFR Ch. I (4-1-04 Edition)

(3) *Limitations.* For intramuscular or intravenous use only. Neomycin is not for use parenterally in food-producing animals because of prolonged residues in edible tissues. Labeling shall bear an appropriate expiration date. For use by or on the order of a licensed veterinarian.¹

[43 FR 48996, Oct. 20, 1978, as amended at 64 FR 403, Jan. 5, 1999]

§ 522.1503 **Neostigmine methylsulfate injection.**

(a) *Specifications.* Neostigmine methylsulfate injection contains two milligrams of neostigmine methylsulfate in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use for treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions. It is a curare antagonist.

(2) It is administered to cattle and horses at a dosage level of 1 milligram per 100 pounds of body weight subcutaneously. It is administered to sheep at a dosage level of 1 to 1½ milligrams per 100 pounds body weight subcutaneously. It is administered to swine at a dosage level of 2 to 3 milligrams per 100 pounds body weight intramuscularly. These doses may be repeated as indicated.

(3) The drug is contraindicated in mechanical, intestinal or urinary obstruction, late pregnancy, and in animals treated with other cholinesterase inhibitors.

(4) Not for use in animals producing milk, since this use will result in contamination of the milk.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 61625, Nov. 19, 1997]

§ 522.1610 **Oleate sodium solution.**

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of sodium oleate.

(b) *Sponsor.* See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(2) The drug is administered by parenteral injection dependent upon the area of response desired. An injection of 1 milliliter will produce a response of approximately 15 square centimeters. Do not inject more than 2 milliliters per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 milliliters.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985]

§ 522.1620 **Orgotein for injection.**

(a) *Specifications.* Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor.* See No. 024991 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses.* (i) It is used in the treatment of soft tissue inflammation associated with the musculoskeletal system.

(ii) It is administered by deep intramuscular injection at a dosage level of 5 milligrams every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.

(iii) Not for use in horses intended for food.

(2) *Dogs.* (i) It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.

(ii) It is administered by subcutaneous injection at a dosage level of 5 milligrams every day for 6 days, and

thereafter, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 32583, Aug. 4, 1976]

§ 522.1642 Oxymorphone hydrochloride injection.

(a) *Specifications.* The drug contains 1 or 1.5 milligrams of oxymorphone hydrochloride per milliliter of aqueous solution containing 0.8 percent sodium chloride.

(b) *Sponsor.* See No. 060951 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is a narcotic analgesic, preanesthetic, anesthetic, and substitute anesthetic adjuvant for intramuscular, subcutaneous or intravenous administration to cats and dogs as follows:

Animal	Body weight (pounds)	Dosage (milligram)
Dogs	2 to 5	0.75
	5 to 15	0.75-1.5
	15 to 30	1.5-2.5
	30 to 60	2.5-4.0
	Over 60	4.0
Cats	Small	0.4-0.75
	Large	0.75-1.5

(2) Do not mix with a barbiturate in the same syringe to preclude precipitation.

(3) It tends to depress respiration. Naloxone hydrochloride and other narcotic antagonists are used to counter over-dosing.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 63 FR 7701, Feb. 17, 1998]

§ 522.1660 Oxytetracycline injection, 200 milligram/milliliter.

(a) *Specifications.* Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.

(b) *Sponsors.* See 000010, 000069, 011722, 053389, 057561, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use—(1) Beef cattle, dairy cattle, and calves including*

preruminating (veal) calves.—(i) *Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of anaplasmosis, severe foot-rot, and advanced cases of other indicated diseases; 9 milligrams per pound of body weight as a single dosage where retreatment for anaplasmosis is impractical; 9 milligrams per pound of body weight as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical; 9 milligrams per pound of body weight as a single dosage for treatment of infectious bovine keratoconjunctivitis.

(ii) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilis* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*. If labeled for use by or on the order of a licensed veterinarian, it may also be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations.* Administer intramuscularly or intravenously at the 3 to 5 milligrams level, intramuscularly at the 9 milligrams level. Sponsors 000010, 011722, 053389, 055529, 057561, and 059130 may also administer subcutaneously at the 3 to 5 milligrams and 9 milligrams levels. Treatment of all diseases should be instituted early and continued for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 1 to 2 milliliters in small calves. Exceeding the highest recommended dose, administering at recommended levels for more than 4

§522.1660a

21 CFR Ch. I (4-1-04 Edition)

consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter. For sponsor 061623: Not for use in lactating dairy cattle. For sponsors 000010, 000069, 011722, 053389, 055529, 057561, and 059130: Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food; use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

(2) *Swine*—(i) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 9 milligrams per pound of body weight as a single dosage where re-treatment for pneumonia is impractical. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(ii) *Indications for use*. Treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(iii) *Limitations*. Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980, as amended at 46 FR 20160, Apr. 3, 1981; 46 FR 27913, May 22, 1981; 52 FR 19502, May 26, 1987; 60 FR 14218, Mar. 16, 1995; 60 FR 29755, June 6, 1995; 61 FR 31028, June 19, 1996; 61 FR 36291, July 10, 1996; 62 FR 13825, Mar. 24, 1997; 62 FR 27692, May 21, 1997; 63 FR 52158, Sept. 30, 1998; 64 FR 23187, Apr. 30, 1999; 64 FR 26670, May 17, 1999; 64 FR 42831, Aug. 6, 1999; 66 FR 13235, Mar. 5, 2001; 67 FR 12471, Mar. 19, 2002; 67 FR 47451, July 19, 2002; 67 FR 72366, 72367, Dec. 5, 2002; 67 FR 78357, Dec. 24, 2002; 68 FR 8153, Feb. 20, 2003; 68 FR 54806, Sept. 19, 2003]

§522.1660a Oxytetracycline injection, 300 milligram/milliliter.

(a) *Specifications*. Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base.

(b) *Sponsor*. See No. 055529 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §556.500 of this chapter.

(d) *Special considerations*. When labeled for use as in paragraph (e)(1)(i)(D) or (e)(1)(i)(E) of this section, labeling shall also bear the following: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(e) *Conditions of use*—(1) *Beef cattle, nonlactating dairy cattle, and calves including preruminating (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of bodyweight (mg/lb BW) per day (day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(B) 5 mg/lb BW/day intramuscularly, subcutaneously, or intravenously for treatment of severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*.

(ii) *Limitations*. Treatment should be continued 24 to 48 hours following remission of disease signs, however, not to exceed a total of four consecutive

days. Do not inject more than 10 mL per site in adult cattle, reducing the volume according to age and body size to 1 to 2 mL in small calves. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amount*. 3 to 5 mg/lb BW/day; 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical. Sows: Administer once 3 mg/lb BW, approximately 8 hours before farrowing or immediately after completion of farrowing.

(ii) *Indications for use*. For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(iii) *Limitations*. Administer intramuscularly. Treatment should be continued 24 to 48 hours beyond remission of disease signs, however, not to exceed a total of 4 consecutive days. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 5 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

[68 FR 54805, Sept. 19, 2003]

§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.

§ 522.1662a Oxytetracycline hydrochloride injection.

(a)(1) *Specifications*. The drug contains 50 milligrams of oxytetracycline

hydrochloride in each milliliter of sterile solution.

(2) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.*; *Hemophilis spp.*; *Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b)(1) *Specifications*. Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline (as oxytetracycline hydrochloride).

(2) *Sponsor*. See 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(a)

Amount. Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Hemophilus spp.*, and *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus spp.* and *Streptococcus spp.* If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale*.

(c) *Limitations.* For 50-milligram-per-milliliter solution, administer intramuscularly or intravenously; for 100-milligram-per-milliliter solution, administer intramuscularly only. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 0.5 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 18 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine*—(a) *Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site. Do not use for more than 4 consecutive days. Discontinue treatment at least 26 days before slaughter.

(c)(1) *Specifications.* The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle and non-lactating dairy cattle. It is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Hemophilus spp.*, *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, acute metritis, and wound infections caused by staphylococcal and streptococcal organisms.

(ii) It is administered to cattle at a dosage level of 3 to 5 milligrams per pound of body weight per day. It may be administered intramuscularly or intravenously from a 50 milligram per milliliter solution. It is administered intravenously from a 100 milligram per milliliter solution. Severe foot-rot and the severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight. Treatment should be continued 24 to 48 hours following remission of disease symptoms, however, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 hours, consult a veterinarian. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the amount injected at each site according to the size of the animal. For very small calves do

not use more than 2 milliliters per injection site.

(iii) Not for use in lactating dairy cattle. Discontinue treatment at least 19 days prior to slaughter. When administered intramuscularly within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site and surrounding tissues.

(d)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) In beef cattle and nonlactating dairy cattle as follows:

(a) It is used for the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Hemophilus spp.*; foot-rot and diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms.

(b) Administer by intravenous or intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and severe forms of the indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended.

(c) If the labeling of the drug bears the statement "Federal law restricts this drug to use by or on the order of a licensed veterinarian," it may include additional directions for use in beef cattle and nonlactating dairy cattle for the treatment of anaplasmosis caused by *Anaplasma marginale*, and anthrax caused by *Bacillus anthracis* in which case the drug is given at 3 to 5 milligrams of oxytetracycline per pound of body weight per day for anthrax, and at 5 milligrams per pound of body weight per day for anaplasmosis.

(ii) In swine as follows:

(a) It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. Administered to

sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(b) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day to swine. Administered to sows at 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after farrowing.

(iii) In poultry (broilers, turkeys, and breeding chickens) as follows:

(a) It is used for the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli*; fowl cholera caused by *Pasteurella multocida*; infectious sinusitis caused by *Mycoplasma gallisepticum*; and infectious synovitis caused by *Mycoplasma synoviae*.

(b) Administered subcutaneously to chickens 1 day to 2 weeks of age at 6.25 milligrams of oxytetracycline per bird per day diluted with 1 part of the drug to 3 parts of sterile water; to chickens 2 to 4 weeks of age using the same diluted product at 12.5 milligrams of oxytetracycline per bird; to chickens 4 to 8 weeks of age without dilution at 25 milligrams of oxytetracycline per bird; to chickens 8 weeks of age (broilers and light pullets) at 50 milligrams of oxytetracycline per bird; to adult chickens at 100 milligrams of oxytetracycline per bird.

(c) Administered subcutaneously to turkeys 1 day to 2 weeks of age and 2 to 4 weeks of age at the same dosage as chickens; to turkeys 4 to 6 weeks of age at 50 milligrams of oxytetracycline as the undiluted product per bird; to turkeys 6 to 9 weeks of age at 100 milligrams of oxytetracycline per bird; to turkeys 9 to 12 weeks of age at 150 milligrams of oxytetracycline per bird; to turkeys 12 weeks of age and older at 200 milligrams of oxytetracycline per bird. In light turkey breeds, no more than 25 milligrams per pound of body weight is administered. For the treatment of infectious sinusitis in turkeys, $\frac{1}{4}$ to $\frac{1}{2}$ milliliter of the drug is injected directly into each swollen sinus depending upon the age of the bird and the severity of the condition. At the time that the sinuses are treated, the drug should also be administered

subcutaneously to the birds according to the dosage schedule given in paragraph (d)(3)(iii)(c) of this section. If refilling of the sinuses occurs, the treatment may be repeated in 5 to 7 days.

(iv) Treatment of all diseases should be instituted early. Treatment should continue for 24 to 48 hours beyond the remission of disease symptoms, but not exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, diagnosis and therapy should be reevaluated.

(v) When injecting intramuscularly in adult livestock, do not inject more than 10 milliliters at any one site. The volume administered per injection site should be reduced according to age and body size so that 1 or 2 milliliters are injected in smaller animals such as small calves and young pigs. Intravenous administration is recommended in cattle when daily dosage exceeds 50 milliliters.

(vi) Treatment must be discontinued at least 5 days prior to slaughter for chickens and turkeys and at least 22 days prior to slaughter for cattle and swine.

When administered intramuscularly to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

(vii) Not for use in lactating dairy animals. Do not administer to laying hens unless the eggs are used for hatching only.

(e)(1) *Specifications.* Each milliliter of sterile solution contains 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Beef cattle and nonlactating dairy cattle—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia*

coli, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(c) *Limitations.* Administer intramuscularly. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 1 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 15 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, administered once, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infections enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine, reducing the volume according to age and body size to 1 to 2 milliliters in young pigs. Discontinue treatment at least 22 days prior to slaughter.

(f) [Reserved]

(g)(1) *Specifications.* Each milliliter of sterile solution contains 100 milligrams of oxytetracycline as oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use.* The drug is used for the treatment of diseases due to oxytetracycline-susceptible organisms as follows:

(i) *Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day.

(b) *Indications for use.* For the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Hemophilus spp.*, or *Klebsiella spp.*

(c) *Limitations.* Administer by intramuscular, intravenous, or subcutaneous injection. In severe forms of the indicated diseases, administer 5 milligrams of oxytetracycline per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 48 hours, consult a veterinarian. Do not inject more than 10 milliliters per injection site intramuscularly in adult cattle; no more than 1 milliliter per site in calves weighing 100 pounds or less. Do not slaughter cattle for 13 days after intramuscular or intravenous treatment, or 2 days after subcutaneous treatment. Exceeding the highest recommended dosage or duration of treatment (not more than 4 consecutive days) may result in residues beyond the withdrawal period. A withdrawal period has not been established for use of this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) *Swine—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by

Leptospira pomona. Sows: As an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations.* Administer intramuscularly. If no improvement is noted within 24 hours, consult a veterinarian. Do not inject more than 5 milliliters per site. Discontinue treatment at least 20 days prior to slaughter.

(h)(1) *Specifications.* Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsors.* See 000010 in § 510.600(c) of this chapter for use of 50 and 100 milligrams/milliliter solution, and see No. 059130 in § 510.600(c) for use of 100 milligrams/milliliter solution.

(3) *Conditions of use—(i) Amount.* The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of severe forms of the indicated diseases.

(ii) *Indications for use.* The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella spp.*; foot-rot and calf diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; wound infections, acute metritis, and traumatic injury caused by staphylococcal and streptococcal organisms.

(iii) *Limitations.* Administer 50-milligram-per-milliliter solution intramuscularly; administer 100-milligram-per-milliliter solution intravenously. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less, do not inject more than 2 milliliters intramuscularly per site. Discontinue treatment at least 22 days

before slaughter. Not for use in lactating dairy animals.

(i)(1) *Specifications.* Each milliliter of sterile solution contains 50 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 059130 in §510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: Administer 3 to 5 milligrams of the oxytetracycline hydrochloride intramuscularly per pound of body weight per day.

(ii) *Indications for use.* The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations.* In severe forms of the indicated diseases, administer the equivalent of 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. In adult livestock, do not inject more than 10 milliliters at any one site. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less inject only 2 milliliters per site. Discontinue treatment at least 18 days before slaughter. Not for use in lactating dairy cattle.

(j) [Reserved]

(k)(1) *Specifications.* Each milliliter of sterile solution contains either 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 061623 in §510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle.* (i) *Amount.* 3 to 5 milligrams per pound of body weight daily, 5 milligrams per pound for anaplasmosis, severe foot rot, and severe forms of other diseases.

(ii) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; acute metritis and wound infections caused by staphylococcal and streptococcal organisms; if labeled for use by or on the order of a licensed veterinarian, it may be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations.* Administer by intravenous injection. Treatment should be continued 24 to 48 hours following remission of disease symptoms, but not to exceed a total of 4 consecutive days. If no improvement occurs within 24 to 48 hours, reevaluate diagnosis and therapy. Discontinue use at least 19 days prior to slaughter. Not for use in lactating dairy cattle.

[40 FR 13858, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §522.1662a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§522.1662b Oxytetracycline hydrochloride with lidocaine injection.

(a) *Specifications.* The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride and 2 percent lidocaine in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 000069 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for use in the treatment of diseases of dogs caused by pathogens sensitive to oxytetracycline hydrochloride including treatment for the following conditions in dogs caused by susceptible microorganisms: Bacterial infections of the urinary tract caused by *Hemolytic staphylococcus*, *Streptococcus* spp., Bacterial pulmonary infections caused by *Brucella bronchiseptica*, *Streptococcus pyogenes*, *Staphylococcus aureus*, secondary bacterial infections caused by *Micrococcus pyogenes* var.

albus, Brucella bronchiseptica, Streptococcus spp.

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983]

§ 522.1680 Oxytocin injection.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 USP units oxytocin.

(b) *Sponsors.* See Nos. 000010, 000856, 059130, 058639, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Obstetrical.* Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cats	0.25 to 0.5	5 to 10.
Dogs	0.25 to 1.5	5 to 30.
Ewes, Sows	1.5 to 2.5	30 to 50.
Cows, Horses	5.0	100.

(ii) *Milk letdown.* Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cows	0.5 to 1.0	10 to 20.
Sows	0.25 to 1.0	5 to 20.

(2) *Indications for use.* Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 63097, Nov. 2, 1979; 45 FR 1019, Jan. 4, 1980, as amended at 52 FR 18691, May 19, 1987; 52 FR 25212, July 6, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 14642, Apr. 11, 1991, 56 FR 16002, Apr. 19, 1991; 59 FR 31139, June 17, 1994; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001; 68 FR 36913, June 20, 2003]

§ 522.1696 Penicillin G procaine implantation and injectable dosage forms.

§ 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 000008, 000856, 010515, 049185, 061623 for use as in paragraph (d)(1) of this section.

(2) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 010515, 059130, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use—(1) Horses, dogs, and beef cattle—(i) Amount—(A) Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses.* 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs.* 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations.* In beef cattle, treatment should be limited to two doses.

§522.1696b

21 CFR Ch. I (4-1-04 Edition)

Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle*—(i) *Amount*. 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use*. (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Corynebacterium pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*Cpyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations*. Limit treatment to two doses. Not for use within 30 days of slaughter.

[66 FR 711, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003]

§522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors*. See sponsor numbers in §510.600(c) of this chapter as follows:

(1) Nos. 010515, 053501, and 059130 for use as in paragraph (d) of this section.

(2) Nos. 055529 and 061623 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See §556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 010515, 053501, 059130, and 061623: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. Not for use in horses intended for food.

(A) For Nos. 010515, 053501, 059130, and 61623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7, all other cattle—4, sheep—8, and swine—6.

(B) For No. 055529: Treatment should not exceed 4 consecutive days. Milk that has been taken during treatment and for 72 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7.

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 68 FR 42589, July 18, 2003]

§522.1696c Penicillin G procaine in oil.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsor*. See No. 053501 in §510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*. (1) *Amount*. Dogs and cats—10,000 units per pound of body weight once daily. Horses—3,000 units per pound of body weight once daily.

(2) *Indications for use*. Treatment of infections of dogs, cats, and horses

caused by penicillin-susceptible organisms such as Streptococci, Staphylococci, and Corynebacteria.

(3) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

§ 522.1698 Pentazocine lactate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains pentazocine lactate equivalent to 30 milligrams of pentazocine base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 0.15 milligram of pentazocine base per pound of body weight per day.

(ii) *Indications for use.* For symptomatic relief of pain due to colic.

(iii) *Limitations.* Administer intravenously or intramuscularly. Intravenous injections are given slowly in the jugular vein. In cases of severe pain, a second dose is recommended intramuscularly 10 to 15 minutes after the initial dose at the same level. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* 0.75 to 1.50 milligrams of pentazocine base per pound of body weight.

(ii) *Indications for use.* For amelioration of pain accompanying post-operative recovery, fracture, trauma, and spinal disorders.

(iii) *Limitations.* Administer intramuscularly only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 31450, June 21, 1977, as amended at 42 FR 36995, July 19, 1977; 47 FR 5409, Feb. 5, 1982; 55 FR 23076, June 6, 1990]

§ 522.1704 Sodium pentobarbital injection.

(a)(1) *Specifications.* Sodium pentobarbital injection is sterile and contains in each milliliter 64.8 milligrams of sodium pentobarbital.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anes-

thetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(ii) The drug is administered intravenously “to effect”. For general surgical anesthesia, the usual dose is 11 to 13 milligrams per pound of body weight. For sedation, the usual dose is approximately 2 milligrams per pound of body weight. For relieving convulsive seizures in dogs, when caused by strychnine, the injection should be administered intravenously “to effect”. The drug may be given intraperitoneally if desired. However, the results of such injections are less uniform. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration. The dose must be reduced for animals showing under-nourishment, toxemia, shock and similar conditions.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) [Reserved]

[40 FR 13858, Mar. 27, 1975, as amended at 45 FR 83483, Dec. 19, 1980; 52 FR 25212, July 6, 1987; 62 FR 61625, Nov. 19, 1997; 66 FR 23588, May 9, 2001]

§ 522.1720 Phenylbutazone injection.

(a) *Specifications.* The drug contains 100 or 200 milligrams of phenylbutazone in each milliliter of sterile aqueous solution.

(b) *Sponsors.* (1) Approval for use of the 200 milligrams per milliliter drug in dogs and horses: See sponsor Nos. 000061, 000856, 058829, and 059130, and 061623 in § 510.600(c) of this chapter.

(2) Approval for use of the 200 milligrams per milliliter drug for use in horses: See sponsor No. 000010 in § 510.600(c) of this chapter.

(3) Approval for use of the 100 milligrams per milliliter drug in dogs and horses: See sponsor No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use for dogs.* (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered intravenously at a dosage level of 10 milligrams per pound of body weight daily in 3 divided

§ 522.1820

21 CFR Ch. I (4-1-04 Edition)

doses, not to exceed 800 milligrams daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use for horses.* (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered intravenously at a dosage level of 1 to 2 grams per 1,000 pounds of body weight daily in 3 divided doses, not to exceed 4 grams daily. Limit intravenous administration to not more than 5 successive days.

(3) Not for use in animals intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1720, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 522.1820 Pituitary luteinizing hormone for injection.

(a) *Specifications.* The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

(2) Preferably given by intravenous injection, it may be administered subcutaneously; dosage is as follows: Cattle and horses, 25 mg; swine, 5 mg; sheep, 2.5 mg, and dogs, 1.0 mg. Treatment may be repeated in 1 to 4 weeks, or as indicated.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications.* Each 1-milliliter ampule of sterile aqueous solution contains 250 milligrams of polysulfated glycosaminoglycan; each 5-milliliter ampule or vial contains 500 milligrams.

(b) *Sponsor.* See No. 010797 in § 510.600(c) of this chapter.

(c) *Conditions of use—horses.* (1) *Indications for use.* Polysulfated glycosaminoglycan is for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.—

(2) *Amount—(i) Intra-articular use (carpal):* 250 milligrams once a week for 5 weeks. The joint area must be shaved, cleaned, and sterilized as in a surgical procedure prior to injection. If the joint reacts with excessive inflammation, after intra-articular treatment, cease therapy.

(ii) *Intramuscular use (carpal and hock):* 500 milligrams every 4 days for 28 days. Injection site must be thoroughly cleansed prior to injection.

(3) *Limitations.* Not for use in horses intended for food. Safe use in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—dogs—(1) Indications for use.* For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(2) *Dosage.* 2 milligrams per pound of body weight by intramuscular injection.

(3) *Limitations.* Administer intramuscularly twice weekly for up to 4 weeks (maximum of 8 injections). Do not exceed recommended dose or regimen. Do not mix with other drugs or solvents. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 53053, Dec. 27, 1989, as amended at 61 FR 54333, Oct. 18, 1996; 62 FR 45158, Aug. 26, 1997]

§ 522.1862 Sterile pralidoxime chloride.

(a) *Chemical name.* 2-Formyl-1-methylpyridinium chloride oxime.

(b) *Specifications.* Sterile pralidoxime chloride is packaged in vials. Each vial

contains 1 gram of sterile pralidoxime chloride powder and includes directions for mixing this gram with 20 cubic centimeters of sterile water for injection prior to use.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.

(2) It is administered as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 milligram per pound of body weight, followed by administration of an additional 0.15 milligram of atropine per pound of body weight administered intramuscularly. Then the appropriate dosage of sterile pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when administered to horses is 2 grams per horse. When administered to dogs and cats, it is 25 milligrams per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime chloride may be given after 1 hour if muscle weakness has not been relieved.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 32061, Aug. 10, 1984]

§ 522.1870 Praziquantel injectable solution.

(a) *Specification*. Each milliliter contains 56.8 milligrams of praziquantel.

(b) *Sponsors*. See 000859 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliliter (56.8 milligrams); if over 25 Pounds, 0.2 milliliter (11.4 milligrams)

per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).

(ii) *Indications for use*. For removal of canine cestodes *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and removal and control of canine cestode *Echinococcus multilocularis*.

(iii) *Limitations*. For subcutaneous or intramuscular use; not intended for use in puppies less than 4 weeks of age; Federal law restricts the drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.

(ii) *Indications for use*. For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(iii) *Limitations*. For subcutaneous or intramuscular injection only. Not intended for use in kittens less than 6 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 10464, Feb. 3, 1981, as amended at 47 FR 6617, Feb. 16, 1982; 58 FR 42853, Aug. 12, 1993; 67 FR 79853, Dec. 31, 2002]

§ 522.1881 Sterile prednisolone acetate aqueous suspension.

(a) *Specifications*. Each milliliter of sterile aqueous suspension contains 25 milligrams of prednisolone acetate.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Conditions of use*. (1) The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations such as bursitis, carpalitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and post-operatively and for various stress conditions

§522.1883

21 CFR Ch. I (4-1-04 Edition)

when corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered to horses intra-articularly at a dosage level of 50 to 100 milligrams. The dose may be repeated when necessary. If no response is noted after 3 or 4 days, the possibility must be considered that the condition is unresponsive to prednisolone therapy. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 milligrams. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 milligrams. The dose may be repeated when necessary after 7 days for two or three doses.

(3) The labeling shall comply with the requirements of §510.410 of this chapter for corticosteroids.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 23032, June 17, 1987]

§522.1883 **Prednisolone sodium phosphate.**

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).

(b) *Sponsor.* See No. 061623 in §510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer intravenously in a dosage of 2 1/2 to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.

(2) *Indications for use.* Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 59881, Oct. 20, 2003]

§522.1884 **Prednisolone sodium succinate injection.**

(a) *Chemical name.* 11 beta, 17, 21-Trihydroxypregna-1, 4-diene-3, 20-dione 21-succinate sodium salt.

(b) *Specifications.* Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10, 20, or 50 milligrams of prednisolone.

(c) *Sponsor.* See No. 000009 in §510.600(c) of this chapter for products containing 10, 20, and 50 milligrams equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (d)(1), (2) (i), (ii), and (iii) of this section.

(d) *Conditions of use.* (1) The drug is intended for the treatment of horses, dogs, and cats.¹

(2)(i) The dosage for horses is 50 to 100 milligrams as an initial dose given intravenously over a period of one-half to 1 minute, or intramuscularly, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.¹

(ii) In dogs, the drug is administered intravenously at a range of 2.5 to 5 milligrams per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) In dogs and cats, the drug may be given intramuscularly for treatment of inflammatory, allergic and less severe stress conditions, where immediate effect is not required, at 1 to 5 milligrams ranging upward to 30 to 50 milligrams in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to 5 days if necessary. If permanent corticosteroid effect is required oral therapy with prednisolone tablets may be substituted.

¹These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 13215, Feb. 20, 1981; 46 FR 33513, June 30, 1981; 52 FR 25212, July 6, 1987; 66 FR 23588, May 9, 2001]

§ 522.1885 Prednisolone tertiary butylacetate suspension.

(a) *Specifications.* Prednisolone tertiary butylacetate (Pregna-1,4-diene-3, 20-dione-11B, 17 α 21-triol 21-(3,3, dimethyl butyrate) suspension contains 20 milligrams of prednisolone tertiary butylacetate per milliliter. It is sterile.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anti-inflammatory agent in horses, dogs, and cats.¹

(2) It is administered to horses intramuscularly at a dosage level of 100 to 300 milligrams and intrasynovially at a dosage level of 50 to 100 milligrams. It is administered intramuscularly to dogs and cats at a dosage level of 1 milligram per 5 pounds of body weight and intrasynovially at a dosage level of 10 to 20 milligrams. Intramuscular re-treatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.¹

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 522.1890 Sterile prednisone suspension.

(a) [Reserved]

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 to 40 milligrams of prednisone.

(2) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* Administer intramuscularly as follows:

(a) *Horses.* 100 to 400 milligrams, repeating if necessary. If no response is observed after 3 to 4 days of therapy, reevaluate diagnosis.¹

(b) *Dogs and cats.* 0.25 to 1.0 milligram per pound of body weight for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.¹

(ii) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.¹

(iii) *Limitations.*¹ Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushings's disease. With infections, use appropriate antibacterial therapy with and for at least 3 days after discontinuance of use and disappearance of all signs of infection. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 13446, Feb. 29, 1980, as amended at 50 FR 6160, Feb. 14, 1985; 52 FR 7832, Mar. 13, 1987]

§ 522.1920 Prochlorperazine, isopropamide for injection.

(a) *Specifications.* Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milligrams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to 0.28 milligrams of isopropamide) in buffered aqueous solution.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 522.1940

21 CFR Ch. I (4-1-04 Edition)

(c) *Conditions of use.* (1) The drug is used in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(2) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	Dosage in Milliliters
Up to 4	0.25
5 to 14	0.5-1
15 to 30	2-3
30 to 45	3-4
45 to 60	4-5
Over 60	6

Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 522.1940 Progesterone and estradiol benzoate in combination.

(a) [Reserved]

(b) *Sponsors.* See 000856 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(ii), (d)(2)(iii), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1) and (d)(2)(i) through (d)(2)(iii)(A) of this section.

(c) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

(d) *Conditions of use.* It is used for implantation in animals as follows:

(1) *Suckling beef calves—(i) Amount.* (A) 100 milligrams of progesterone and 10 milligrams of estradiol benzoate in four pellets per implant dose.

(B) 100 milligrams of progesterone and 10 milligrams of estradiol benzoate in four pellets with 29 milligrams of tylosin tartrate as a local antibacterial in one pellet per implant dose.

(ii) *Indications for use.* Increased rate of weight gain.

(iii) *Limitations.* For use in suckling beef calves (at least 45 days of age) up to 400 pounds of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction.

(2) *Steers—(i) Amount.* (A) 200 milligrams of progesterone and 20 milligrams estradiol benzoate in eight pellets per implant dose.

(B) 200 milligrams progesterone and 20 milligrams estradiol benzoate in eight pellets with 29 milligrams tylosin tartrate as a local antibacterial in one pellet per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* (A) For animals weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal.

(B) For additional improvement in rate of weight gain in steers fed in confinement for slaughter, reimplant at approximately day 70.

(3) *Steers fed in confinement for slaughter—(i) Amount.* Reimplant 200 milligrams of progesterone and 20 milligrams of estradiol benzoate on approximately day 70 following an initial implant of 100 milligrams of progesterone and 10 milligrams of estradiol benzoate or 200 milligrams of progesterone and 20 milligrams of estradiol benzoate.

(ii) *Indications for use.* For additional improvement in rate of weight gain.

(iii) *Limitations.* For subcutaneous ear implantation.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 48659, Oct. 20, 1983; 49 FR 13873, Apr. 9, 1984; 51 FR 21746, June 16, 1986; 52 FR 45312, Nov. 27, 1987; 53 FR 7406, Feb. 21, 1989; 55 FR 13769, Apr. 12, 1990; 59 FR 49808, Sept. 30, 1994; 61 FR 5507, Feb. 13, 1996; 62 FR 8372, Feb. 25, 1997; 63 FR 45945, Aug. 28, 1998; 64 FR 48294, Sept. 3, 1999]

§ 522.1962 Promazine hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

(b) *Sponsor.* In § 510.600(c) of this chapter, see No. 000008 for conditions of use as in paragraph (c)(1)(i) of this section; see No. 000856 for conditions of use as in paragraph (c)(1)(ii) of this section; see No. 061623 for conditions of use as in paragraph (c)(1)(iii) of this section.

(c) *Conditions of use—(1) Amounts and indications for use.* (i) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats 1 to 3 milligrams per pound of body

weight, every 4 to 6 hours as a tranquilizer or preanesthetic.

(ii) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats at 1 to 2 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic in dogs and cats prior to worming, or to prevent motion sickness in dogs.¹

(iii) To horses intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, as a tranquilizer and preanesthetic, as required.

(2) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18962, Mar. 27, 1981, as amended at 68 FR 59881, Oct. 20, 2003]

§ 522.2002 Propiopromazine hydrochloride injection.

(a) *Chemical name.* 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications.* Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05–0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5507, Feb. 13, 1996]

§ 522.2005 Propofol injection.

(a) *Specifications.* The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraphs (c)(1) and (c)(2) of this section. See No. 000074 in § 510.600(c) of this chapter for use as in paragraph (c)(1) of this section.

(c) *Conditions of use—(1) Dogs.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to effect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 8.0 to 13.2 milligrams per kilogram (3.6 to 6.0 milligrams per pound). For the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 4.4 milligrams per kilogram (0.5 to 2.0 milligrams per pound).

§ 522.2012

21 CFR Ch. I (4-1-04 Edition)

The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding cats have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66582, Dec. 18, 1996, as amended at 62 FR 61625, Nov. 19, 1997; 63 FR 24420, May 4, 1998; 64 FR 13510, Mar. 19, 1999]

§ 522.2012 Prostalene solution.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of prostalene.

(b) *Sponsor.* No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—Horses.* (1) It is used in mares for the control of estrus.

(2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 26854, June 30, 1976, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.2063 Pyrilamine maleate injection.

(a) *Specifications.* The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.

(b) *Sponsors.* See No. 000061 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(i) of this section; see No. 061623 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(ii) of this section.

(c) *Conditions of use.* (1) It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.¹

(2)(i) It is administered intramuscularly, subcutaneously, or

intravenously. Local injection at the site of insect bites may be indicated in severe cases. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours whenever necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.¹

(ii) It is administered intravenously. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours if necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.¹

(3) Do not use in horses intended for food purposes.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975; 41 FR 9150, Mar. 3, 1976, as amended at 42 FR 13549, Mar. 11, 1977; 42 FR 61256, Dec. 2, 1977; 51 FR 41477, Nov. 17, 1986; 52 FR 7832, Mar. 13, 1987; 54 FR 1164, Jan. 12, 1989; 68 FR 59881, Oct. 20, 2003]

§ 522.2100 Selenium, vitamin E injection.

(a)(1) *Specifications.* The drug is an emulsion containing in each milliliter, 5.48 milligrams sodium selenite (equivalent to 2.5 milligrams selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use for the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(ii) The drug is administered by intravenous or deep intramuscular injection in divided doses in 2 or more sites in the gluteal or cervical muscles at a dosage level of 1 milliliter per 100 pounds of body weight and may be repeated at 5 to 10 day intervals.

(iii) Do not use in horses intended for food.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug contains in each milliliter 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium), 50 milligrams of

¹These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use as an aid in alleviating and controlling inflammation, pain and lameness associated with certain arthropathies in dogs.

(ii) The drug is administered subcutaneously or intramuscularly in divided doses in 2 or more sites at a dosage level of 1 milliliter per 20 pounds of body weight with a minimum dosage of ¼ milliliter and a maximum dosage of 5 milliliters. The dosage is repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 milliliter per 40 pounds of body weight with a minimum dosage of ¼ milliliter which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter contains 2.19 milligrams of selenite sodium (equivalent to 1 milligram selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Calves: 2.5 to 3.75 milliliters per 100 pounds of body weight. Lambs 2 weeks of age or older: 1 milliliter per 40 pounds, minimum 1 milliliter. Ewes: 2.5 milliliters per 100 pounds. Sows: 1 milliliter per 40 pounds. Weanling pigs: 1 milliliter per 40 pounds, minimum 1 milliliter.

(ii) *Indications for use.* Calves, lambs, and ewes: prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Sows and weanling pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use. Not for use in newborn pigs. Do not use in pregnant ewes. Calves: Discontinue use 30 days before treated calves are slaughtered for

human consumption. Lambs, ewes, sows, or pigs: Discontinue use 14 days before treated lambs, ewes, sows, or pigs are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter contains 10.95 milligrams selenite sodium (equivalent to 5 milligrams selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsor.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Breeding beef cows: 1 milliliter per 200 pounds of body weight during the middle third of gestation, and 30 days before calving. Weanling calves: 1 milliliter per 200 pounds of body weight.

(ii) *Indications for use.* Weanling calves and breeding beef cows: For the prevention and treatment of selenium-tocopherol deficiency syndrome.

(iii) *Limitations.* For subcutaneous or intramuscular use. Discontinue use 30 days before treated cattle are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter contains 0.55 milligram selenite sodium (equivalent to 0.25 milligram selenium), 50 milligrams (68 U.S.P. units) vitamin E.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Newborn lambs: 1 milliliter. Lambs 2 weeks of age or older: 4 milliliters. Baby pigs: 1 milliliter (or treat the sow during the last week of pregnancy).

(ii) *Indications for use.* Lambs: for prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Baby pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use only. Discontinue use 14 days before treated animals are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 57 FR 21209, May 19, 1992; 58 FR 57556, Oct. 26, 1993; 60 FR 57833, Nov. 22, 1995; 64 FR 27916, May 24, 1999]

§ 522.2112

21 CFR Ch. I (4-1-04 Edition)

§ 522.2112 Sometribove zinc suspension.

(a) *Specifications.* Each single-dose syringe contains 500 milligrams (mg) sometribove zinc in a prolonged-release suspension.

(b) *Sponsor.* See No. 000911 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Inject 500 mg every 14 days starting during the 9th or 10th week (57 to 70 days) after calving and continue until the end of lactation.

(2) *Indications for use.* To increase production of marketable milk in healthy lactating dairy cows.

(3) *Limitations.* Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Inject subcutaneously. Avoid injections within 2 weeks of expected slaughter to minimize injection site blemishes on carcass. There is no milk discard or preslaughter withdrawal period. Use may reduce pregnancy rates and increase days open. Treated cows are at an increased risk for mastitis and higher milk somatic cell counts. Use care to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Cows treated with this product may have more enlarged hocks and disorders of the foot region. Use may reduce hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

[58 FR 59947, Nov. 12, 1993, as amended at 67 FR 18085, Apr. 15, 2002; 68 FR 62006, Oct. 31, 2003]

§ 522.2120 Spectinomycin dihydrochloride injection.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. Each milliliter of the drug contains the following amount of spectinomycin activity from spectinomycin dihydrochloride pentahydrate:

(1) 5 milligrams when used as provided in paragraph (d)(1) of this section.

(2) [Reserved]

(3) 100 milligrams when used as provided in paragraphs (d) (2), (3), and (4) of this section.

(b) *Sponsor.* In § 510.600 of this chapter, see No. 059130 for conditions of use as in paragraph (d) of this section, and see No. 000009 for conditions of use as in paragraph (d)(2) and (d)(4) of this section.

(c) *Special considerations.* The quantity of spectinomycin referred to in this section refers to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* It is administered as spectinomycin dihydrochloride pentahydrate as follows:

(1) Subcutaneously in the treatment of 1-to-3-day-old turkey poults at the rate of 1 to 2 milligrams per poult as an aid in the prevention of mortality associated with Arizona group infection.

(2) Subcutaneously in the treatment of 1-to-3-day old:

(i) Turkey poults at the rate of 5 milligrams per poult as an aid in the control of chronic respiratory disease (CRD) associated with *E. coli*.

(ii) Baby chicks at the rate of 2.5 to 5 milligrams per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae*, *S. typhimurium*, *S. infantis*, and *E. coli*.

(3) Intramuscularly in the treatment of dogs:

(i) At a dosage level of 2.5 milligrams to 5.0 milligrams per pound of body weight twice daily. Treatment may be continued for 4 days. For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

(ii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Administer single injection of 0.1 milliliter (10 milligrams) subcutaneously in nape of neck of 1- to 3-day-old turkey poults as an aid in control of airsacculitis associated with

M. meleagridis sensitive to spectinomycin.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 9273, Mar. 7, 1978; 46 FR 18964, Mar. 27, 1981; 47 FR 14149, Apr. 2, 1982; 61 FR 5507, Feb. 13, 1996; 61 FR 31028, June 19, 1996; 65 FR 45877, July 26, 2000; 66 FR 22118, May 3, 2001]

§ 522.2121 Spectinomycin sulfate solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams of spectinomycin.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Dose.* 10 to 15 milligrams per kilogram of body weight, at 24-hour intervals for 3 to 5 consecutive days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (pneumonia) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(iii) *Limitations.* For subcutaneous injection in the neck. Do not inject more than 50 milliliters at each site. Do not slaughter within 11 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause residues in milk. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 24107, May 1, 1998]

§ 522.2150 Stanozolol sterile suspension.

(a) *Specifications.* Each milliliter of sterile suspension contains 50 milligrams of stanozolol.

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Used as an anabolic steroid treatment in dogs, cats, and horses.

(2) Administered to dogs and cats by deep intramuscular injection in the thigh at weekly intervals, for several weeks. For cats and small breeds of

dogs, 25 milligrams. For larger dogs, 50 milligrams.

(3) Administered to horses by deep intramuscular injection in the gluteal region at weekly intervals, for not more than 4 weeks; 25 milligrams per 100 pounds of body weight.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 46101, Oct. 6, 1975, as amended at 42 FR 36995, July 19, 1977; 55 FR 23076, June 6, 1990]

§ 522.2200 Sulfachlorpyridazine.

(a) *Chemical name.* *N*¹-(6-Chloro-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range 190 °C to 191 °C.

(c) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.630 of this chapter.

(e) *Conditions of use.* It is used for injection into calves as follows:

(1) *Amount.* 30 to 45 milligrams per pound of body weight per day.

(2) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(3) *Limitations.* Administer as the sodium salt of sulfachlorpyridazine intravenously in aqueous solution for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 5 days after the last treatment.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 522.2220 Sulfadimethoxine injection.

(a)(1) *Specifications.* Sulfadimethoxine injection containing 400 milligrams per milliliter.

(2) *Sponsor.* (i) See No. 000069 in § 510.600(c) of this chapter for conditions of use as in paragraphs (a)(3)(i) through (a)(3)(iii) of this section.

(ii) See No. 057561 for conditions of use as in paragraph (a)(3) of this section.

(iii) See No. 059130 for use as in paragraph (a)(3)(iii) of this section.

(3) *Conditions of use.* (i) It is used or intended for use in dogs and cats as follows:

§ 522.2240

21 CFR Ch. I (4-1-04 Edition)

(a) For the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by Streptococci, Staphylococci, Escherichia, Salmonella, Klebsiella, Proteus, or Shigella organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.

(b) It is administered by intravenous or subcutaneous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours.

(c) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) It is used or intended for use in horses as follows:

(a) For the treatment of respiratory disease caused by Streptococcus equi (strangles).

(b) It is administered by intravenous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours until the patient is asymptomatic for 48 hours.

(c) Not for use in horses intended for food.

(d) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) It is used or intended for use in cattle as follows:

(a) For the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot-rot.

(b) It is administered by intravenous injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

(c) Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter.

(d) Tissue damage may result from perivascular infiltration.

(b) [Reserved]

(c)(1) *Specifications.* Sulfadimethoxine containing 100 milligrams per milliliter.

(2) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used or intended for use in the treatment of sulfadimethoxine-susceptible bacterial infections in dogs.

(ii) It is administered by subcutaneous, intramuscular, or intravenous injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours thereafter. Continue treatment until the animal is free from symptoms for 48 hours.

(iii) For use by or on the order of a licensed veterinarian.

(d) *Related tolerances.* See § 556.640 of this chapter.

[40 FR 13858, Mar. 27, 1975, as amended at 40 FR 34112, Aug. 14, 1975; 40 FR 42007, Sept. 10, 1975; 50 FR 254, Jan. 3, 1985; 53 FR 40728, Oct. 18, 1988; 54 FR 30205, July 19, 1989; 58 FR 38972, July 21, 1993; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 23128, Apr. 29, 1997; 62 FR 35076, June 30, 1997]

§ 522.2240 Sulfaethoxy pyridazine.

(a) *Chemical name.* N¹-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range of 180 °C to 186 °C.

(c) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used for injection into cattle as follows:

(1) *Amount.* 2.5 grams per 100 pounds of body weight per day.

(2) *Indications for use.* Treatment of respiratory infection (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(3) *Limitations.* Administer intravenously for not more than 4 days; or first treatment may be followed by 3 days of treatment with sulfaethoxy pyridazine in drinking water, feed, or tablet in accordance with § 558.579(e) or §§ 520.2240a(e) and 520.2240b(e) of this chapter; as sodium sulfaethoxy pyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used

Food and Drug Administration, HHS

§ 522.2404

for food; for use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 11011, Mar. 15, 1976; 67 FR 78355, Dec. 24, 2002]

§ 522.2260 Sulfamethazine injectable solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of sulfamethazine sodium.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *NAS/NRC status.* The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(e) *Conditions of use*—(1) *Amount.* 20 milliliters for each 50 pounds of body weight (100 milligrams per pound) initially, 20 milliliters per 100 pounds of body weight (50 milligrams per pound) daily thereafter for cattle.

(2) *Indications for use.* For cattle for treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis and acute metritis (*Streptococcus* spp.) when caused by one or more pathogenic organisms sensitive to sulfamethazine.

(3) *Limitations.* For intravenous use only. Not for use in lactating dairy animals. Withdraw medication from cattle 10 days prior to slaughter for food. If symptoms persist for 2 or 3 days, consult a veterinarian. Adequate water intake is important for animals treated with sulfonamides. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days.

[46 FR 62055, Dec. 22, 1981, as amended at 67 FR 78355, Dec. 24, 2002]

§ 522.2340 Sulfomyxin.

(a) *Specifications.* Sulfomyxin for injection is sterile. It is derived from the antibiotic substance produced by the

growth of *Bacillus polymyxa* or is the same substance produced by any other means.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.700 of this chapter.

(e) *Conditions of use.* (1) It is used or intended for use in chickens and turkeys as an aid in the treatment of disease caused or complicated by *E. coli*, such as colibacillosis and complicated chronic respiratory disease.

(2) It is administered by subcutaneous injection as follows:

Age of birds in days	Antibiotic activity	
	Chickens (units)	Turkeys (units)
1 to 14	12,500	12,500
15 to 28	25,000	25,000
29 to 63	50,000	50,000
Over 63	50,000	100,000

(3) A second injection may be given 3 days later if symptoms persist.

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter; do not treat turkeys within 7 days of slaughter.

§ 522.2404 Thialbarbitone sodium for injection.

(a) *Specifications.* Thialbarbitone sodium for injection when reconstituted with sterile distilled water provides 94 milligrams of thialbarbitone sodium per milliliter of solution.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered as a general anesthetic in surgical procedures on dogs, cats, swine, sheep, cattle, and horses. The drug is used for procedures of relatively short duration. However, the period of anesthesia can be lengthened by slower initial injection and supplemental administration during surgery.

(2) It is administered intravenously. The drug is injected slowly to dogs, cats, cattle, sheep, and swine. For horses, it is recommended that a pre-anesthetic sedation be administered to the horse 30 minutes before the drug is administered. The drug is then injected

§ 522.2424

rapidly and completely. The drug is used at the following dosage levels:

Species	Weight of animal in pounds	Dosage in milligrams per pound
Dog	Over 50	14.1
Do	30-50	18.8
Do	10-30	23.5
Do	Under 10	28.2
Cat	31.3-37.6
Horse	6.3-7.8
Cattle and swine	6.7-9.4
Calves and sheep	9.4-11.8

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2424 Sodium thiamylal for injection.

(a) *Specifications.* The drug is a sterile dry powder. It is reconstituted aseptically with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) *Sponsors.* See code Nos. 000010 and 000856 in § 510.500(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(2) When diluted aseptically to the desired concentration and administered intravenously to effect, the average single dose is:

(i) Dogs and cats: 8 milligrams per pound of body weight (when used with a preanesthetic, generally one-half the normal dose).

(ii) Swine: 40 milligrams per 5 pounds of body weight.

(iii) Horses: Light anesthesia, 1 gram per 500 pounds to 1,100 pounds of body weight; deep anesthesia, 1 gram per 300 pounds of body weight (40 milligrams per 12 pounds of body weight).

(iv) Cattle: Short duration, 20 milligrams per 5 pounds of body weight; longer duration, 40 milligrams per 7 pounds of body weight.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) NAS/NRC status: The conditions of use specified in this paragraph are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may re-

quire bioequivalency and safety information.

[40 FR 25812, June 19, 1975, as amended at 49 FR 8434, Mar. 7, 1984; 53 FR 23390, June 22, 1988; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 522.2444 Sodium thiopental implantation or injectable dosage forms.

§ 522.2444a Sodium thiopental for injection.

(a) *Specifications.* The drug contains sodium thiopental sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(2) It is administered as follows:

(i) For brief anesthesia (6 to 10 minutes) a dosage of 6 to 9 milligrams per pound of body weight is suggested.

(ii) To obtain anesthesia of 15 to 25 minutes duration the suggested dosage is 10 to 12 milligrams per pound of body weight.

(iii) Use of a preanesthetic tranquilizer or morphine will decrease the dosage of sodium thiopental required, provide for smoother induction and smoother recovery, and sometimes prolong the recovery period. If morphine is used as a preanesthetic agent the dose of the barbiturate can be reduced as much as 40 to 50 percent. When a tranquilizer is administered the barbiturate dosage can be reduced 10 to 25 percent.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2444b Sodium thiopental, sodium pentobarbital for injection.

(a) *Specifications.* Each gram of the drug contains 750 milligrams of sodium thiopental and 250 milligrams of sodium pentobarbital sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(2) It is administered as follows:

(i) For total anesthesia, it is given at approximately 10 to 12 milligrams per pound of body weight over a period of 3.5 to 5 minutes.

(ii) When preanesthetic medication is used, it is important to wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually $\frac{1}{2}$ to $\frac{2}{3}$ the normal amount is adequate.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 47 FR 14149, Apr. 2, 1982; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.

(a) *Specifications.* Tiletamine hydrochloride and zolazepam hydrochloride for injection when reconstituted with sterile distilled water provides tiletamine hydrochloride and zolazepam hydrochloride equivalent to 50 milligrams of tiletamine base and 50 milligrams of zolazepam base per milliliter of solution.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* It is used for restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes) requiring mild to moderate analgesia.

(2) *Amount.* Expressed as milligrams of the drug combination:

(i) In healthy dogs: An initial intramuscular dosage of 3 to 4.5 milligrams per pound of body weight for diagnostic purposes; 4.5 to 6 milligrams per pound of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 milligrams per pound of body weight.

The maximum total safe dose is 13.6 milligrams per pound of body weight.

(ii) In healthy cats: An initial intramuscular dosage of 4.4 to 5.4 milligrams per pound of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 milligrams per pound of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 milligrams per pound of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 milligrams per pound of body weight.

(3) *Limitations.* Discard unused reconstituted solution after 48 hours. Not for use in dogs and cats with pancreatic disease, or with severe cardiac or pulmonary dysfunction. Not for use in pregnant animals. Not for use in cats suffering with renal insufficiency. The dosage should be reduced in geriatric dogs and cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15328, Apr. 9, 1982, as amended at 51 FR 24142, July 2, 1986; 67 FR 67521, Nov. 6, 2002]

§ 522.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Special considerations.* (1) Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes.

(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use—(1) Cattle—(i) Amount.* 10 mg per kilogram (kg) body

§ 522.2474

weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (P.) haemolytica*.

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 28 days of last treatment.

(2) *Sheep*—(i) *Amount.* 10 mg/kg body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia (P.) haemolytica*.

(iii) *Limitations.* Do not slaughter within 28 days of last treatment.

[67 FR 72367, Dec. 5, 2002]

§ 522.2474 Tolazoline hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or 1.8 milligrams per pound (4 milliliters per 100 kilograms or 4 milliliters per 220 pounds).

(ii) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(iii) *Limitations.* The safety of Tolazine™ has not been established in pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of Tolazine™ has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in food-producing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease)

should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 25785, May 23, 1996]

§ 522.2476 Trenbolone acetate.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraphs (d)(1) and (d)(2) of this section.

(2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(ii), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*—(i) *Amount.* Use 126 days prior to slaughter; should be reimplanted once after 63 days.

(A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount.* Use last 63 days prior to slaughter.

(A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

[66 FR 47961, Sept. 17, 2001]

§ 522.2477 Trenbolone acetate and estradiol.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraphs (d)(1), (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(i)(C), (d)(2)(i)(E), (d)(2)(iii), and (d)(3) of this section.

(2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(3) No. 000856 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii).

(c) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount.* (A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(E) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg es-

tradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(F) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

(2) *Heifers fed in confinement for slaughter—(i) Amount.* (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(B) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 8 pellets, each of 7 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraphs (d)(2)(ii)(A) of this section.

(C) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(D) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(E) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use.* (A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

§522.2478

21 CFR Ch. I (4-1-04 Edition)

(3) *Pasture cattle (slaughter, stocker, and feeder steers and heifers)*—(i) *Amount.* (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Not for use in animals intended for subsequent breeding or in dairy animals.

[60 FR 4376, Jan. 23, 1995, as amended at 61 FR 29480, June 11, 1996; 61 FR 41499, Aug. 9, 1996; 62 FR 28629, May 27, 1997; 64 FR 42597, Aug. 5, 1999; 64 FR 48294, Sept. 3, 1999; 65 FR 10706, Feb. 29, 2000; 65 FR 26748, May 9, 2000; 65 FR 45879, July 26, 2000; 65 FR 70663, Nov. 27, 2000; 66 FR 47961, Sept. 17, 2001; 67 FR 5724, Feb. 7, 2002; 67 FR 78358, Dec. 24, 2002; 68 FR 42250, July 17, 2003; 68 FR 48785, Aug. 15, 2003; 68 FR 55200, 55201, Sept. 23, 2003; 69 FR 500, Jan. 6, 2004; 69 FR 7116, Feb. 13, 2004; 69 FR 12271, Mar. 16, 2004; 69 FR 13735, Mar. 24, 2004]

§522.2478 **Trenbolone acetate and estradiol benzoate.**

(a) *Specifications.* Each implant dose consists of:

(1) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(2) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(b) *Sponsor.* See No. 000856 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §§556.240 and 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter.* (i) For an implant as described in paragraph (a)(1) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(C) *Limitations.* Implant subcutaneously in ear only.

(ii) For an implant as described in paragraph (a)(2) of this section:

(A) *Amount.* 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain.

(C) *Limitations.* Implant subcutaneously in ear only.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate (as described in paragraph (a)(1) of this section).

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Not for dairy or beef replacement heifers.

[67 FR 78972, Dec. 27, 2002]

§522.2483 **Sterile triamcinolone acetonide suspension.**

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.

(b) *Sponsor.* See 000010 and 053501 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats*—(a) *Intramuscular or subcutaneous.* Single injection of 0.05 to 0.1 milligram (mg.) per pound of body weight in inflammatory, arthritic, or allergic disorders. Single injection of 0.1 mg. per pound of body weight in dermatologic disorders. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.¹

(b) *Intralesional.* 1.2 to 1.8 mg., divided in several injections, spaced around the lesion at 0.5 to 2.5 centimeters apart depending on the size. At any one site the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(c) *Intra-articular and intrasynovial.* Single injection of 1 to 3 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Horses*—(a) *Intramuscular or subcutaneous.* Single injection of 0.01 to 0.02 mg. per pound of body weight. Usual dose, 12 to 20 mg.

(b) *Intra-articular and intrasynovial.* Single injection of 6 to 18 mg. dose, dependent on size of joint and severity of

symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(2) *Indications for use.* Treatment of inflammation and related disorders in dogs, cats, and horses;¹ and management and treatment of acute arthritis and allergic and dermatologic disorders in dogs and cats.

(3) *Limitations.* (i) Do not use in viral infections. With bacterial infections, appropriate antibacterial therapy should be used.

(ii) Do not use in animals with tuberculosis, chronic nephritis, or cushingoid syndrome, except for emergency therapy.

(iii) Not for use in horses intended for food.

(iv) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(v) Do not use in the treatment of laminitis.

(vi) Intra-articular injection in equine leg injuries may produce osseous metaplasia.

(vii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 4976, Feb. 7, 1978, as amended at 50 FR 41490, Oct. 11, 1985; 52 FR 1903, Jan. 16, 1987; 53 FR 40728, Oct. 18, 1988; 62 FR 35077, June 30, 1997]

§ 522.2582 Triflupromazine hydrochloride injection.

(a) *Specifications.* Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs, cats, and horses to relieve

¹These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.¹

(2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body weight daily to a maximum dose of 100 milligrams.¹

(3) Not for use in horses intended for food.¹

(4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 522.2610 Trimethoprim and sulfadiazine sterile suspension.

(a)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 240 milligrams (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine).

(2) *Sponsor.* See 000061 and 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* One milliliter (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine) per 20 pounds (9 kilograms) of body weight per day.

(ii) *Indications.* For dogs for treatment of acute urinary tract infections,

¹These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

§ 522.2615

acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus*.

(iii) *Limitations*. For subcutaneous use in dogs only; administer once every 24 hours, or for severe infections, after an initial dose, administer half the normal daily dose every 12 hours; continue therapy 2 to 3 days after clinical signs of infection have subsided; if no improvement is seen in 3 to 5 days, reevaluate diagnosis; injection may be used alone or in conjunction with oral dosing; not recommended for use for more than 14 days; a complete blood count should be done for prolonged use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. Each milliliter of sterile aqueous suspension contains 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine (as the sodium salt)).

(2) *Sponsor*. See 000856 and 011716 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage*. Two milliliters (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine) per 100 pounds (45 kilograms) of body weight per day.

(ii) *Indications*. For horses where systemic anti-bacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations*. For intravenous use; administer as single, daily dose for 5 to 7 days; daily dose may also be halved and given morning and evening; continue acute infection therapy 2 to 3 days after clinical signs have subsided; if no improvement of acute infections is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count should be done periodically for prolonged use; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 241, Jan. 4, 1983, as amended at 48 FR 23180, May 24, 1983; 48 FR 42809, Sept. 20, 1983; 61 FR 5507, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

21 CFR Ch. I (4–1–04 Edition)

§ 522.2615 Tripeleppamine hydrochloride injection.

(a) *Specifications*. Each milliliter of aqueous solution contains 20 milligrams of tripeleppamine hydrochloride.

(b) *Sponsor*. See Nos. 053501 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.741 of this chapter.

(d) *Conditions of use*—(1) *Amount*—(i) *Dogs, cats, and horses*. For intramuscular use only at a dose of 0.5 milligram per pound of body weight.

(ii) *Cattle*. Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) *Indications for use*. For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(3) *Limitations*. Do not use in horses intended for food purposes. Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997]

§ 522.2640 Tylosin injectable dosage forms.

§ 522.2640a Tylosin injection.

(a) *Specifications*. Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled “Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,” which is incorporated by reference. Copies are

available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Sponsors.* (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) *NAS/NRC status.* These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use—(1) Beef cattle and nonlactating dairy cattle—(i) Amount.* 8 milligrams per pound of body weight once daily.

(ii) *Indications for use.* Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Corynebacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Corynebacterium pyogenes*.

(iii) *Limitations.* Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 10 milliliters per site. Do not use in lactating dairy cattle. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not administer within 21 days of slaughter.

(2) *Swine—(i) Amount.* 4 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations.* Administer intramuscularly for not more than 3

consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(3) *Dogs and cats—(i) Amount.* 3 to 5 milligrams per pound of body weight at 12- to 24-hour intervals.

(ii) *Indications for use—(a) Dogs.* Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by *Staphylococci* spp., hemolytic *Streptococci* spp., and *Pasteurella multocida*.

(b) *Cats.* Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin susceptible organisms.

(iii) *Limitations.* For intramuscular use only. If there is no response to therapy in 5 days, diagnosis and treatment should be reassessed. Use a 50-milligram-per-milliliter solution only. Dogs and cats receiving a dose of less than 50 milligrams (1 milliliter) should be dosed with a tuberculin syringe. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 48643, Oct. 2, 1981, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 49841, Dec. 5, 1985; 50 FR 50292, Dec. 10, 1985; 53 FR 40728, Oct. 18, 1988; 59 FR 14365, Mar. 28, 1994; 62 FR 35077, June 30, 1997; 68 FR 24879, May 9, 2003]

§ 522.2662 Xylazine.

(a) *Specifications.* Each milliliter (mL) of solution contains xylazine hydrochloride equivalent to:

- (1) 20 milligrams (mg) xylazine.
- (2) 100 mg xylazine.
- (3) 300 mg xylazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(2) No. 000856 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(3) Nos. 000859 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1); and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(4) No. 061690 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section; and product described in paragraph (a)(3) of this section as in paragraphs (d)(3)(i), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 0.5 mg/pound (lb) intravenously or 1.0 mg/lb subcutaneously.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(2) *Horses*—(i) *Amount.* 0.5 mg/lb intravenously or 1.0 mg/lb intramuscularly.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(iii) *Limitations.* Not for use in horses intended for food.

(3) *Elk and deer*—(i) *Amount.* Administer intramuscularly, by hand syringe, or by syringe dart, in the heavy muscles of the croup or shoulder as follows:

(A) Elk (*Cervus canadensis*): 0.25 to 0.5 mg/lb.

(B) Mule deer (*Odocoileus hemionus*), sika deer (*Cervus nippon*), and white-tailed deer (*Odocoileus virginianus*): 1 to 2 mg/lb.

(C) Fallow deer (*Dama dama*): 2 to 4 mg/lb.

(ii) *Indications for use.*

(A) To produce sedation, as an analgesic, and as a preanesthetic to local anesthesia.

(B) To produce sedation, accompanied by a shorter period of analgesia. May be used to calm and facilitate handling of fractious animals for diagnostic procedures, for minor surgical procedures, for therapeutic medication for sedation and relief of pain following injury or surgery, and as a preanesthetic to local anesthetic. At the recommended dosages, can be used in conjunction with local anesthetics, such as procaine or lidocaine.

(iii) *Limitations.* Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.

[68 FR 26206, May 15, 2003]

§ 522.2670 Yohimbine injectable.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) *Sponsor.* See 061690 in § 510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.

(1) *Amount.* 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) *Indications for use.* To reverse the effects of xylazine in dogs.

(3) *Limitations.* For intravenous use in dogs only. Not for use in food-producing animals. Safety of use in pregnant dogs or in dogs intended for breeding has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See 053923 in § 510.600(c) of this chapter for use of 5 milligrams per milliliter solution in deer and elk.

(1) *Amount.* 0.2 to 0.3 milligram per kilogram of body weight.

(2) *Indications for use.* As an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(3) *Limitations.* For intravenous use only. Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 8543, Feb. 16, 1993, as amended at 60 FR 57832, Nov. 22, 1995]

§ 522.2680 Zeranol.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.760 of this chapter.

(d) *Conditions of use—(1) Beef cattle—(i) Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use—(A)* For increased rate of weight gain and improved feed conversion in weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers.

(B) For increased rate of weight gain in suckling calves.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in bulls intended for reproduction or in dairy animals. Do not use before 1 month of age or after weaning in heifers intended for reproduction.

(2) *Feedlot lambs—(i) Amount.* 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in breeding animals. Do not implant animals within 40 days of slaughter.

(3) *Steers fed in confinement for slaughter—(i) Amount.* 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only.

(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)—(i) Amount.* 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only.

[59 FR 19639, Apr. 25, 1994; 60 FR 26360, May 17, 1995, as amended at 62 FR 61625, Nov. 19, 1997; 64 FR 46840, Aug. 27, 1999; 67 FR 6867, Feb. 14, 2002]

§ 522.2690 Zinc gluconate.

(a) *Specifications.* Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(b) *Sponsor.* See No. 067647 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* The volume injected into each testicle is based on testicular width as determined by measuring each testicle at its widest point using a metric scale (millimeter) caliper.

(2) *Indications for use.* Intratesticular injection for chemical sterilization of 3- to 10-month-old male dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26995, May 19, 2003]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

- 524.86 Amitraz liquid.
- 524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.
- 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.
- 524.390 Chloramphenicol ophthalmic and topical dosage forms.
- 524.390a Chloramphenicol ophthalmic ointment.
- 524.390b Chloramphenicol ophthalmic solution.
- 524.390d Chloramphenicol-prednisolone ophthalmic ointment.
- 524.402 Chlorhexidine ointment.
- 524.450 Clotrimazole cream.
- 524.463 Copper naphthenate solution.
- 524.520 Cuprimyxin cream.
- 524.575 Cyclosporine ophthalmic ointment.
- 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.
- 524.660a Dimethyl sulfoxide solution.
- 524.660b Dimethyl sulfoxide gel.
- 524.770 Doramectin.
- 524.802 Enrofloxacin, silver sulfadiazine emulsion.